

Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*



Prepared for:

Agency of Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
<http://www.ahrq.gov>

Contract No. 75Q80120D00019**Prepared by:**

Dave Boston, MD ¹
Deborah Cohen, PhD ²
Julie Stone, MPA ¹
Erica Edwards, MS ¹
Angelea Brown, MPH ¹
Martha Snow, MPH ³
LeAnn Michaels ³
Lourdes González, MPH, CPH ¹

1 OCHIN, Inc., Portland, OR

2 Department of Family Medicine, Oregon Health & Science University, Portland, OR

3 Oregon Rural Practice-based Research Network, Oregon Health & Science University,
Portland, OR

AHRQ Publication No. AHRQ 22-0013 December 2021

Disclaimer: This practical guide was funded under contract number 75Q80120D00019 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The authors are solely responsible for this document's findings and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this product as an official position of AHRQ or of the U.S. Department of Health and Human Services. None of the authors have any affiliation or financial involvement that conflicts with the material presented in this practical guide.

Public Availability Notice: This document is made publicly available by AHRQ and may be used and reprinted without permission in the United States for noncommercial purposes, unless materials are clearly noted as copyrighted in the document. No one may reproduce copyrighted material without the permission of the copyright holders. Users outside the United States must get permission from AHRQ to reprint or translate this product. Anyone wanting to reproduce this product for sale must contact AHRQ for permission.

Acknowledgments

We would like to give gratitude to the Technical Expert Panel who has given us permission to share their knowledge and experience in this practical guide:

- Victoria Tiase, PhD, RN-BC, New York-Presbyterian Hospital
- James McCormack, PhD, Oregon Health & Science University
- James Pantelas, Patient Partner, Michigan
- Richelle Koopman, MD, MS, University of Missouri
- Matthew Roman, DPT, Duke Health
- Steven Kassakian, MD, MS, FACP, Humana Health


Table of Contents

FOLIO 1: Introduction: What is Patient-Generated Health Data and Why is it Important?	1
Key Learning Concepts.....	2
What is PGHD?.....	4
PGHD Referred to in This Guide.....	5
What Does It Mean to Integrate PGHD into the EHR?	7
Benefits of PGHD Integration	7
PGHD Increases Patient Engagement and Satisfaction	8
PGHD Integration into the EHR Provides a Fuller Picture of Patient Health ..	8
Better Care Quicker: PGHD for More Timely, Personalized Interventions	9
Trends in Support of PGHD Integration and Use	10
Health Equity and Integrating PGHD.....	11
FOLIO 2: Assessing Readiness for PGHD Program Implementation.....	13
Key Learning Concepts.....	14
Preparing to Launch a PGHD Program in Your Practice	15
Where to Start?	15
Assess Staff Readiness	15
Assess Patient Readiness	17
Determine What Support Your Patients Need to Collect PGHD	17
ACTIVITY 2.1: Organizational Readiness.....	20
ACTIVITY 2.2: Gauge Motivation and Concerns from Patients and Colleagues	23

ACTIVITY 2.3: Roadmap to PGHD Implementation: Key Considerations Relevant to Patient Participation	25
FOLIO 3: Assembling a Team to Manage Change	28
Key Learning Concepts.....	29
Build the Team: Identify Stakeholders and Find Your Champions	30
Who Are Your Stakeholders?	30
The Role of the Champion in Change Management	30
Where to Find Champions: Who is Already Using PGHD in Clinical Care?...	31
Designate a PGHD Coordinator to Support Patients and Staff.....	31
Include Community Partner Organizations and Agencies.....	32
ACTIVITY 3.1: Assemble Your Team of Champions.....	34
ACTIVITY 3.2: Assemble a PGHD Workgroup	42
FOLIO 4: Making the Right PGHD and Information Technology Decisions for Your Practice	43
Key Learning Concepts.....	44
Choose Information Technology that Meets Your Needs	45
Selecting Devices for Your PGHD Program.....	46
Pathways to PGHD Integration into the EHR.....	46
Consider Your Approach to Patients Choosing Their Own Devices.....	48
Legal, Compliance, and Security Frameworks	48
Data Governance	50
Privacy and Security.....	51
ACTIVITY 4.1: Roadmap to PGHD Implementation: Key Health IT, Legal, Compliance, and Security Considerations	54

FOLIO 5: Evaluating the Costs of PGHD Implementation.....	61
Key Learning Concepts.....	62
Big Picture Factors that Influence Your Program’s Financial Health	63
Billing and Reimbursement.....	63
Explore Other Sources of Funding	64
Return on Investment	65
Incentive and Quality Reporting Programs	66
Develop a Budget to Implement, Grow, and Sustain Your Implementation	67
Considerations for Your Cost Spreadsheet.....	67
ACTIVITY 5.1: Roadmap to PGHD Implementation:	
Key Financial, Reimbursement, and Reporting Considerations.....	71
FOLIO 6: Steps to Successfully Implement a PGHD Program.....	73
Key Learning Concepts.....	74
Developing Your PGHD Implementation.....	75
Set Realistic and Measurable Goals for Your PGHD Implementation	75
Effectively Engage Your Target Group of Patients	77
Develop Diagrams and Detailed Workflows	78
Learn from Your Experience Before Scaling Your PGHD Implementation	80
Rapid-Cycle Testing and End-User Feedback	82
Support Staff Awareness Through Training and Messaging.	87
Scale with a Strong Internal and External Communication Plan.....	87
Share Success Stories.....	89
Monitoring Environmental Factors	89

Resources for Implementation, Scaling, and Environmental Monitoring Your PGHD Program	89
ACTIVITY 6.1: Bringing It All Together: Your PGHD Implementation ...	91
ACTIVITY 6.2: Craft Your First SMART Goal	95
ACTIVITY 6.3: Develop Workflows	96
ACTIVITY 6.4: Evaluate and Refine	98
ACTIVITY 6.5: Scale Up and Monitor	100
References	102



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*

FOLIO 1: Introduction: What is Patient-Generated Health Data and Why is it Important?



Estimated reading time: 11 minutes

IN THIS FOLIO

Key Learning Concepts

- Definition of patient-generated health data (PGHD).
- Integration of PGHD into the electronic health record (EHR).
provides clinical decision making support.
- Benefits of PGHD include increased patient engagement, fuller pictures of health, and more timely interventions.
- The uptick in virtual care adoption provides support for PGHD.
- Efforts to attain health equity should be baked into program planning.
- How to Use This Practical Guide.

This guide is intended to support ambulatory care settings of all types—including offices of physicians and other health professionals, outpatient departments, community health centers, ambulatory surgical centers, and urgent care clinics and specialty clinics—in the design and implementation of successful PGHD programs that can improve patient outcomes.

It is intended to accompany [Integrating Patient-generated Digital Health Data into Electronic Health Records in Ambulatory Care Settings: An Environmental Scan](#), which summarizes the most current evidence on PGHD integration into clinical settings.¹

The guide is organized into folios that help your ambulatory practice—in partnership with your patients—navigate the many steps from design, to launch, to maintenance of a successful, sustainable PGHD integration program. Folios include planning considerations and practical activities to support your effort to deploy a new and complex care delivery modality into your practice.

Included in this practical guide:

Folio 1: Introduction: What is Patient-Generated Health Data and Why is it Important?

Folio 2: Assessing Readiness for PGHD Program Implementation

Folio 3: Assembling a Team to Manage Change

Folio 4: Making the Right PGHD and Information Technology Decisions for Your Practice

Folio 5: Evaluating the Costs of PGHD Implementation

Folio 6: Steps to Successfully Implement a PGHD Program

Because your success will be highly linked to the capacity and interests of your practice staff and the unique needs and preferences of your patients, PGHD programs are likely to differ greatly across settings. The content of this guide is designed to support your unique journey—pick and choose content in this guide that is useful to you. You may choose to read these folios from beginning to end or to skip around to review content that has the greatest relevance to your current needs. Additionally, the guide is completely searchable by keyword. Simply type **CONTROL + F (COMMAND + F for Mac users)** to open the search bar.

To make learning more meaningful, consider applying data from your own practice to inform decisions and develop practical solutions to real challenges. Use real-life examples and patient stories to inform your decisions around the design and implementation of your program.

Tips, Ideas, and Activities

Look for special icons that callout quick tips and ideas for easy scanning.



Tip



Idea

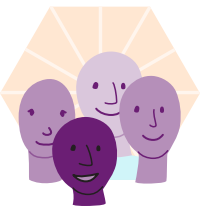
Learning exercises and checklists invite active participation to tailor solutions to your needs.



Activity

Write on a printout or type directly into the pages using free Adobe Reader software.

Let's get started.



What is PGHD?

The Office of the National Coordinator for Health Information Technology (ONC) defines PGHD as “health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.”² This includes patient-reported data gathered from surveys, and data generated from remote monitoring devices, such as mobile health apps and wearable devices.

PGHD Referred to in This Guide

For the purposes of this practical guide, we will consider the following categories and domains of PGHD:

- Data gathered through queries or prompts—
 - Health and Treatment Histories
 - Lifestyle Choices or Social Histories
 - Patient-Reported Outcomes
- Patient-Measured Biometric Data



Health and Treatment Histories

Health and treatment histories may influence screening and diagnosis of disease, care planning, and prescribing. This includes a patient-reported history of personal and family conditions, illnesses, and surgeries. This information is commonly captured at check-in for new patients and is reviewed or updated as needed. ³

Comprehensive health and treatment histories can also include patient-reported information about mental and behavioral health, such as nutrition; physical activity level; alcohol, tobacco, and drug use; sleep habits; stress management; and healthy relationships. ⁴ Social history may include occupation, education, living situation, military service, hobbies, spiritual beliefs, and activities of daily living. ⁵



PGHD regarding the patient's health-related quality of life, functional status, health behaviors, symptoms, and symptom burden are collected via self-report. These are often called **patient-reported outcomes (PROs)**.

PROs are defined as “information providing the status of a patient's health outcomes that comes directly from the patient, without interpretation of that patient's response by a clinician or anyone else.” ⁶



There are a wide range of validated instruments to collect PROs. For example, [PROMIS®](#) (Patient-reported Outcomes Measurement Information System) is an inventory of validated, person-centered measures for adults and children that includes physical, mental, and social health measures in English and Spanish, and may be administered on paper, computer applications or software, or tablet apps.

Patients may be asked to complete these instruments in the office, via the patient portal, or through an app. PROs play a vital role in patient care, yet may not be routinely captured in the EHR. ⁷



Biometric Data

Patient-generated biometric data include vital sign measurements and other indicators of health such as blood pressure, blood glucose, and weight. These data can be captured through patient-facing technology in between visits to better inform care, provide trends, and monitor chronic conditions. Depending on the device and vendor, biometric data may be integrated as discrete data into the EHR.

Table 1: Biometric Data Types and Patient-Facing Devices

Type	Patient-Facing Device Example
Blood pressure	Blood pressure cuff
Blood glucose	Blood glucose monitor
Physical activity	Wearable, smartphone
Heart rate	Heart rate monitor
Blood oxygen saturation	Pulse oximeter
Weight	Bluetooth/Wi-Fi enabled scale
Sleep	Actigraphy monitor
Temperature	Remote temperature monitor

NOTE: We will not address implantable devices such as pacemakers in our discussion.

What Does It Mean to Integrate PGHD into the EHR?

In keeping with the Clinical Decision Support (CDS) Five Rights,⁸ PGHD need to be actionable at the time of clinical decision making to make the greatest impact on patient care. PGHD may indicate the need for further screening, medical intervention, behavioral counsel, or medication adjustments.

When PGHD are integrated into the EHR, they are added to a patient's health record and can be used for clinical decision-making. These data can provide a more complete picture that informs longitudinal, continuous care.

PGHD can be input manually into the EHR by patients, clinicians, or staff, or transmitted directly from the patient to the EHR via a third-party vendor. Data will be entered either into a discrete data field or as free text. This depends on the type of PGHD and the capabilities of the EHR and third-party vendor device. PGHD collection and integration functionality may include an additional cost from your vendor. If PGHD are entered into discrete field, your EHR may contain native applications that enable clinicians and patients to view PGHD data in dashboards that assist with visualizing trends.⁹

The rate and frequency by which PGHD may be transmitted and ingested into the EHR vary by device. Some PGHD, particularly biometric data related to chronic diseases such as diabetes or hypertension, may generate a high volume of data. To condense large volumes of data points, batch transfers and binning algorithms can bucket data into units that can be more easily managed by your EHR. High volumes of data, such as readings from a continuous glucose monitor, are generally translated into data visualizations.



Benefits of PGHD Integration

Integration of PGHD into the EHR has the potential to inform clinical decision making and improve ambulatory care. In ambulatory settings, the health benefits of PGHD are most evident when these data are leveraged and aligned with a specific clinical focus.¹

PGHD can facilitate patient and clinician management of conditions such as diabetes, high blood pressure, chronic obstructive pulmonary disease, congestive heart failure, and pregnancy.

PGHD can help improve the care of homebound patients, those with mobility limitations, and patients with transportation barriers.

PGHD Increases Patient Engagement and Satisfaction

Using PGHD to inform medical care decisions offers patients the opportunity to become more engaged, empowered, and connected to their health.¹⁰ Increased patient engagement and empowerment can contribute to better health outcomes and increased patient satisfaction with their care.^{11, 12, 13, 14} Further, PGHD provides patients reassurance in their self-management.^{1, 15}

PGHD Integration into the EHR Provides a Fuller Picture of Patient Health

For most patients, visits with their doctors are short and infrequent. The health data collected in the office during these visits provide a few isolated snapshots that may not be representative of patients' health as experienced in the routine course of daily life. PGHD has the potential to offer clinicians, patients, and caregivers a more complete and nuanced picture of the patient's health within the context of everyday living.

Three Clinical Use Cases for Home Blood Pressure Readings

Home blood pressure monitoring is an excellent example of PGHD integrated into the EHR to enhance diagnosis and treatment of hypertension.^{16, 17}

Fifty-four percent of U.S. adults diagnosed with hypertension report measuring their blood pressure at home. Evidence suggests that home blood pressure predicts cardiovascular outcomes even after accounting for in-clinic blood pressures, prompting the U.S. Preventive Service Task Force (USPSTF) and professional society guidelines to promote inclusion of home data for hypertension diagnosis and management.^{1, 18} Dr. Richelle Koopman, a leading investigator in PGHD research at the University of Missouri School of Medicine in Columbia, Missouri, says, "Patient home blood pressure is an independent, valuable, predictive piece of information."¹⁹

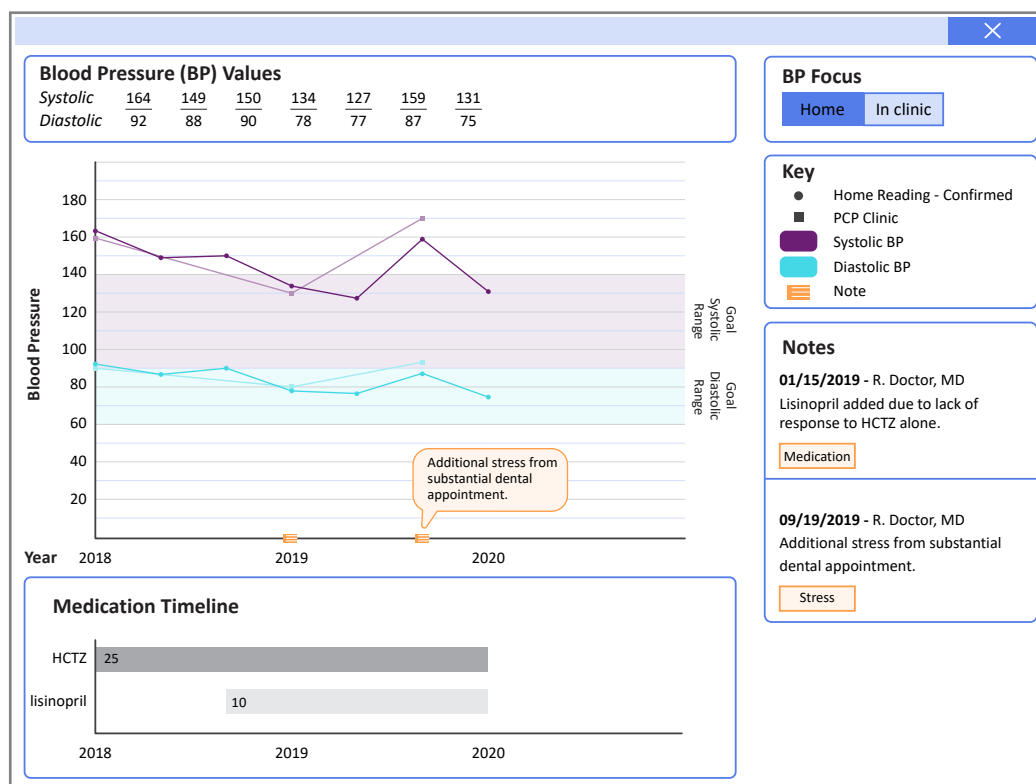
Three clinical use cases for home blood pressure readings include:

- Diagnosing hypertension per the [USPSTF recommendation](#).
- Monitoring the effects of medication changes to control hypertension.
- Detecting hypotensive episodes.^{19, 20}

Better Care Quicker: PGHD for More Timely, Personalized Interventions

When your PGHD integration is supported by EHR-based data visualization tools, clinicians and patients can visualize trends and spot irregularities earlier, creating opportunities to make care plan adjustments. Dr. Richelle Koopman explains, “People receive care during a visit, and then they go too long between visits before we make another intervention. This goes for treatment of everything from depression to hypertension. There are ways that PGHD—patient feedback about what’s going on—can help us get to better care and improvement quicker.”¹⁹

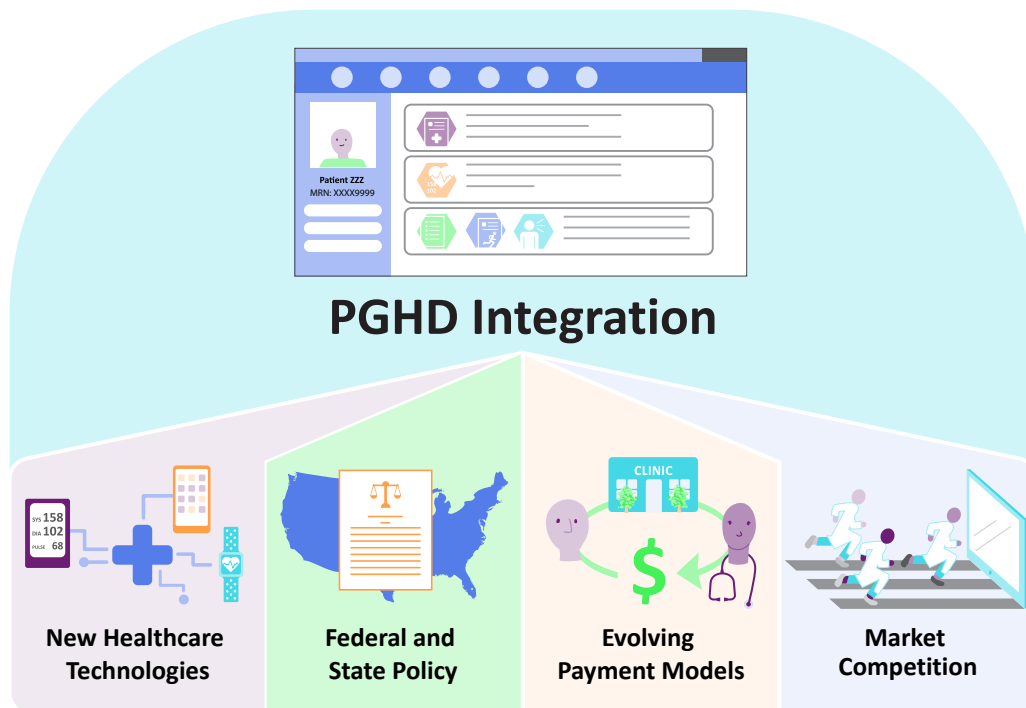
Figure 1. Example of an Idealized Data Visualization for Blood Pressure in the EHR²¹



For more detailed information on the health benefits associated with the incorporation of PGHD, please see the [environmental scan](#).

Trends in Support of PGHD Integration and Use

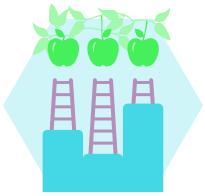
Figure 2. Drivers of PGHD Integration into the EHR in Ambulatory Care Practices



Emerging healthcare technologies, Federal and State policies, evolving payment models, and an increasingly competitive virtual healthcare marketplace, taken together with the Nation's collective pivot to virtual care during the COVID-19 pandemic, are among the factors accelerating the shift to and support for PGHD integration.

This shift is further supported by technology advancement, including the development and lower cost of advanced biosensors, greater broadband coverage, widespread use of smartphones, and digital solutions that streamline interoperability.

This is not new territory for clinicians, who have relied on PGHD to inform treatment decisions for decades. For example, home blood pressure measurement is not new, and it can effectively identify white coat effect and masked hypertension.^{16, 17}



Health Equity and Integrating PGHD


Through increased communication, fuller data, earlier intervention, improved self-management, and higher engagement, the use of PGHD in ambulatory clinics may have the potential to improve care for patients who are disproportionately impacted by chronic disease—those with higher social risk factors such as low income, food insecurity, and housing instability.^{22, 23, 24}

Yet, disparities in access and ability to use patient portals, devices, and other technologies persist. These tools are not equitably distributed or available to those who may benefit from PGHD most—a truth which has become more exposed throughout the COVID-19 pandemic.^{25, 26, 27} Factors that potentially exacerbate the digital divide include broadband and device access, digital health literacy, and lack of inclusive design.¹


Include health equity in your planning to help your practice identify barriers to PGHD adoption within your patient population. This could be internet access, cost of devices, language, or technical proficiency barriers.

The following are some considerations for building health equity into your PGHD program:

- Keep barriers in mind when selecting PGHD types and devices. If specific devices or methods are not optional, lessen their impact with baked-in resources.
- Refer eligible patients to subsidized internet programs.
- Look for Federal and State grant opportunities.
- Create or find a device loaner library to reduce costs.
- Produce educational support in multiple languages to bridge language gaps.
- Rely on visuals to help illustrate instructions and troubleshooting advice.
- Community partners can help fill other gaps. This could be a local library who can host device technical support classes, or a peer support group that can share tips and tricks.
- When recruiting patients to participate in a PGHD program, offer the same opportunities to all patients. Don't assume lack of interest based on factors such as income, living situation, or education. These patients may be eager and ideal candidates.



This guide offers tips and ideas for ambulatory care practices of diverse sizes and resource capacities, and provides suggestions for serving patients with limitations in digital literacy, internet access, and English-language proficiency.



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*

FOLIO 2: Assessing Readiness for PGHD Program Implementation



Estimated reading time: 11 minutes

IN THIS FOLIO

Key Learning Concepts

- PGHD integration may mark a significant change in your practice.
- Incorporate perspectives of staff into PGHD implementation planning.
- Incorporate patient perspectives on PGHD to achieve greater equity and satisfaction.
- Assess your practice and patients for readiness.

Active Learning Exercises

- ACTIVITY 2.1: Organizational Readiness
- ACTIVITY 2.2: Gauge Motivation from Patients and Colleagues
- ACTIVITY 2.3: Roadmap to PGHD Implementation:
Key Considerations Relevant to Patient Participation



Preparing to Launch a PGHD Program in Your Practice

Imagine a scenario in which patients use the patient portal to securely enter their home blood pressure readings directly into the EHR, where they can be visualized by both the clinical team and the patient. These visualizations can include graphs and dashboards viewable within the EHR. They can enable you to easily view trends in clinic blood pressures and home blood pressures over time. Annotations can clearly show when patients started and stopped hypertension medications, as well as the impacts of these actions. In just moments, you and your patients can assess blood pressure management. Medication modifications, if needed, can be made quickly, possibly even without the need for an office visit.

Reaching this point in PGHD implementation requires numerous operational changes in your practice that will impact your EHR, clinical teamwork, workflows, care delivery, and patient engagement in care.

Where to Start?

It should not be difficult to find areas in your practice that would likely benefit from the integration of PGHD into your EHR. Often, the more difficult task is prioritizing the best opportunities for starting your program and addressing potential barriers to successful implementation.

Assess Staff Readiness

We recommend starting by talking with your colleagues about their interest and experience with PGHD. Make sure to hear from your care team of all different professional roles and backgrounds. Ask them what they know about PGHD. Ask them if they have ever used it in practice. If they have, ask them about their experiences. How important is it to them to integrate PGHD into clinical care? Where do they think their patients might gain the most benefits from doing so?

Your colleagues might even identify possible challenges to PGHD implementation.

Challenges may include:

- Low confidence in patient data collected in the home.
- Inadequate financial and/or staff resources to implement a new PGHD program.
- Concerns that staff time needed to review PGHD will increase clinical staff workload.
- Uncertainty about billing and reimbursement.
- Lack of knowledge about how to select the right devices for patient use.
- Reservations about security and privacy of patient data.

The concerns you may surface about PGHD integration are important to understand, as these can pose substantial challenges to obtaining buy-in and successful PGHD implementation. These experiences need to be carefully considered and addressed as you begin PGHD program implementation.

Explore your organization's readiness in more depth with **Activity 2.1: Organizational Readiness** beginning on page 20.



Idea: Take an inventory of ways PGHD is currently being used.

Taking inventory of the ways PGHD is currently utilized in your practice will help you assess:

- Where you currently are on the continuum of PGHD integration.
- Which clinicians and/or conditions are already relying on PGHD in some form.
- Which clinicians and/or other staff have familiarity with PGHD integration and/or recognize the value of its integration.

When you conduct the organizational readiness assessment in **Activity 2.1**, be sure to investigate what types of PGHD the practice already uses routinely in clinical care.

Assess Patient Readiness

A critical part of clinic readiness for PGHD implementation includes the readiness of your patients. As the creators of PGHD, patients are indispensable stakeholders. Therefore, PGHD implementation should be aligned with patient needs, resources, barriers, and concerns.¹ It is important to engage patients early in the PGHD implementation process as stakeholders with a prominent voice.¹

Start by assessing your patient's motivation and challenges to collecting PGHD with **Activity 2.2: Gauging Motivation from Patients and Colleagues.**



Idea: Work with your patient and family advisory council.

Consider convening a patient and family advisory council or engaging patient advocates as part of your baseline readiness assessment. Be sure to include patients who are eager to engage in PGHD collection and those who might be more reticent. Understanding the obstacles patients may face to using health devices and uploading PGHD will be critical.

Determine What Support Your Patients Need to Collect PGHD

A patient readiness assessment can identify the different types of support patients may need to use digital PGHD devices, collect data, and upload it into your EHRs via the patient portal. If there are unmet needs, consider what solutions you can fold in as you plan your implementation.

Essential Resources Patients Need to Benefit from PGHD

There are several factors that can limit patient's use of PGHD.

- Digital health literacy (e-health literacy)
- Health literacy
- Language proficiency
- Technical proficiency
- Access to broadband or Wi-Fi
- Access to devices (i.e., smartphone, tablet, remote monitoring device)

Other possible barriers to using PGHD tools must be considered are:

- Low dexterity
- Visual or hearing impairment
- Intellectual/developmental disability
- Barriers related to age/culture/illness/chronic condition

You may find that some patients who could benefit from PGHD will need extra support. Learn from your patients what kind of additional support would be helpful. Your practice may be able to provide appropriate patient education, instructions, and technical support in multiple media formats and languages that can enable a broader range of patients access to the benefits of PGHD.^{28 29}



Idea: Look outside the clinic walls to meet needs.

Consider hosting help sessions or partnering with community-based organizations located in the neighborhoods where your patients live to deliver culturally appropriate education and support.

These may include:




























- YMCA
- Public libraries
- Community centers
- Faith-based organizations
- School-based health centers

Federal programs may also provide resources. This could include:

- [Lifeline program for affordable telecommunications](#)
- [Emergency Broadband Benefit \(EBB\) Program](#)

Including a mix of community partners will expand your capacity to engage patients with various backgrounds and needs. Community partners may also be able to address certain shortfalls by providing services such as Wi-Fi hotspots. See **Figure 1** on page 19 for various potential solutions to common patient barriers to PGHD use.

Figure 1: Potential solutions to common patient barriers to PGHD use

Barriers						
		 Lack of Internet access	 Low health IT proficiency	 Dexterity	 Vision	 Language
Solutions	 Patient education and instructions					
	 Technical support					
	 Multiple media					
	 Multiple languages					
	 Community partnerships					
	 Wi-Fi hotspots					



ACTIVITY 2.1: Organizational Readiness

The purpose of this activity is to begin to assess your organization's readiness for change. Ask clinicians, clinical staff, the practice manager, and other healthcare professionals to think about their attitudes toward PGHD integration into the EHR. This information will inform your approach to PGHD program planning and help prioritize your staff's needs. Consider compiling findings into a recommendation for your executive leadership.

Instructions: Type answers directly into the field or print to handwrite.

What PGHD are currently in use at your practice? For example:

- What are examples of routine care in which patients bring PGHD to their appointments?
- What are examples of PGHD providers routinely request from patients to inform clinical care?
- What are examples of screenings, surveys, or questionnaires routinely collected as part of clinical care?
- What forms of remote patient monitoring are in use?

Collect information to fill in the answers.

PGHD IN USE AT YOUR PRACTICE

PGHD Patients provide (e.g., blood glucose, blood pressure, weight):

PGHD clinicians request (e.g., measurements, questionnaires):

Screenings, surveys, or questionnaires (e.g., PHQ-2, SDoH, health history):

Remote patient monitoring (e.g., heart rate, blood pressure):

PRIORITY AND EXCITEMENT

Describe your organization's level of enthusiasm for PGHD integration into the EHR.

Why does your organization want to focus on PGHD?

What will your practice gain by integrating PGHD?

What resources will executive leadership commit to providing (budget, staffing, dedicated time, etc.) to execute this project?

Do you have a patient and family advisory committee or other venues to recruit patient stakeholders or elicit input?

Who can be identified as a PGHD Coordinator from your practice who can champion this work?

Which processes will be used to execute new programs and quality improvement?

Do you have a process for developing policy, protocol, training, and other needs for a new health IT implementation?

What are staff attitudes about PGHD integration into the EHR to improve patient care?

Do staff have capacity to learn new workflows, protocols, and messaging for PGHD integration into the EHR?



ACTIVITY 2.2: Gauge Motivation and Concerns from Patients and Colleagues

The purpose of this activity is to help your practice understand the motivations and concerns of patients and staff around implementing a PGHD program. It can be helpful to dig into the reasons patients and staff might be initially resistant and be prepared with solutions to address barriers. Findings may also help inform choices and decisions as your executive leadership steers your practice through PGHD implementation.

Instructions: Type answers directly into the field or print to handwrite.

MOTIVATION TO PARTICIPATE

Gather information from patients and colleagues about their motivations to participate. ³⁰

What conditions are patients most likely to manage and improve by collecting PGHD? (e.g., hypertension, depression, diabetes)

Does PGHD integration fill a patient care gap or unmet patient care need?

Are patients seeking new ways to communicate and share data about their conditions?

CHALLENGES

Conversely, it is important to get an idea of what your patient's hesitations may be.

Are your patients worried about privacy and security?

Are they concerned about degree of added burden?

Do they have access to reliable internet?

Are the tools or devices cost-prohibitive?

Do your patients rely on interpretation services?

Do your patients have low-English proficiency?

Do your patients have adequate digital literacy?

Do your patients have physical barriers such as low dexterity, visual or hearing impairment, or age-related barriers?

Do your patients have intellectual or developmental disability?

Are there cultural barriers?



ACTIVITY 2.3: Roadmap to PGHD Implementation: Key Considerations Relevant to Patient Participation

Use the following list of key considerations to guide decision-making and identify potential gaps in your PGHD program implementation.

Your responses from previous activities in this folio will help guide you through these considerations. This will begin forming your customized roadmap to implementation and assist your work in **Folio 6, Activity 6.1: Bringing It All Together: Your PGHD Implementation.**

Instructions: After each consideration, use the form field to record notes. Type directly into the field or print to handwrite.

PATIENT PARTICIPATION CONSIDERATIONS

- Does this offering fill a patient care gap or meet an unmet patient care need?
- How do you identify patients or patient populations that are good/poor candidates?
- What are the motivations of patients to use PGHD? (e.g., improve BP control, monitor symptoms of depression or anxiety, IVF/fertility medicine, lose weight)

- Do patients have sufficient resources to benefit from PGHD? (e.g., digital literacy, health literacy, English proficiency, access to broadband or Wi-Fi, means to purchase devices)

- Are supports available to fill gaps (e.g., subsidized smartphones and data plans, lending library of wireless devices, interpreter services, caregiver assistance)


- Do many of your patients use smartphones?

- Have you considered how you might address inequities in access and care among your patients?

ACCESS TO IT INFRASTRUCTURE AND INTERNET CONSIDERATIONS

- Is broadband widely available in your community?

- Are there community partners (conventional and nonconventional) that might potentially serve as sites for patient education and technical assistance?
- Have you considered how you might leverage resources external to your clinic in order best engage your patients?
- Who in your practice can provide technical assistance to patients?



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*



FOLIO 3: Assembling a Team to Manage Change



FOLIO 3

Assembling a Team to Manage Change

Estimated reading time: 9 minutes

IN THIS FOLIO

Key Learning Concepts

- Build the team: Identify stakeholders and find your champions.
- A PGHD Coordinator could be crucial to success.
- External partners are powerful allies.

Active Learning Exercises

- ACTIVITY 3.1: Identify Your Team of Champions
- ACTIVITY 3.2: Assemble a Core PGHD Workgroup



FOLIO 3

Assembling a Team to Manage Change

In **Folio 2**, you explored the readiness and enthusiasm of your practice to undertake PGHD implementation, identified if you are already receiving any type of PGHD, and spoke with patients and staff about what matters most to them. All of this was done to help you prioritize and make informed decisions.

Folio 3 focuses on a next key step in the change management process: how to identify and assemble your team that will lead the change.



Build the Team: Identify Stakeholders and Find Your Champions

Who Are Your Stakeholders?

To start, identify the individuals, departments, vendors, contractors, and other groups that will directly or indirectly be touched by or have expertise to lend to the PGHD implementation. This includes considering the resources, skills, and expertise you will need to carry out PGHD implementation and ensure its sustainability.

Who will influence the success or failure of your implementation? These are the stakeholders in your PGHD program implementation. **Activity 3.1: Assembling Your Team of Champions** has a comprehensive, customizable list of possible stakeholders and champions. Depending on the size of your operation, one person may fill multiple roles or one role might be filled by multiple people. **Activity 3.2** offers a table where you can name and organize your PGHD design and implementation core team.

The Role of the Champion in Change Management

Champions provide crucial support for change efforts in ambulatory care settings, often facilitating change through their influence, knowledge, and skills in concert with ready enthusiasm.³¹ Champions lead program planning and implementation, build buy-in, connect resources, and assist in overcoming obstacles.³² Your champions will be indispensable resources as you develop, implement, and grow your PGHD program.



Where to Find Champions: Who is Already Using PGHD in Clinical Care?

In **Folio 2**, you identified if you have examples of current PGHD applications in your practice. If you are already using PGHD applications, the clinicians, patients, and clinical support staff already engaged in these activities are prime candidates for your team of champions.

Promising staff champions include:

- Staff with a particular interest in PGHD tools and apps.
- Staff who use PGHD tools and apps to improve their own health and fitness.
- Staff that have been involved in leading health IT solutions or customizing your EHR build within your practice.

As a way of building support and consensus early on, you might even consider influential staff who have resisted change or virtual care ideas in the past.

Promising patient champions include:

- Those who have shared PGHD from a fitness tracker, app, or device
- Patient populations with obvious clinical use cases (e.g., patients with diabetes who use continuous glucose monitors or patients self-monitoring their blood pressure).



Tip: If you have a clinical informaticist on staff, bring in this individual. A clinical informaticist can assist your practice in identifying the best strategy to ensure patients can easily upload their data into the EHR and in making the right data available at the right time to impact clinical decision making.

Designate a PGHD Coordinator to Support Patients and Staff

Formally name and resource the PGHD coordinator as a key role within the program. This person supports the implementation team in numerous ways, from project management to quality improvement (QI).



Responsibilities of the PGHD Coordinator

The responsibilities that can be assigned to a PGHD Coordinator include:

- Recruit and align stakeholders.
- Provide critical project management support.
- Develop cultural norms.
- Build policies and workflows.
- Organize staff training.
- Track rates of PGHD uptake and patterns of use.

See **Activity 3.1: Assemble Your Team of Champions** for a more detailed list of responsibilities and tasks for the PGHD Coordinator and other roles.



Idea: Assign multiple PGHD coordinators.

For large practices, you may consider identifying more than one staff person to the role of PGHD Coordinator. Consider engaging distinct program coordinators, such as people who support patients with hypertension, diabetes, and congestive heart failure.



Idea: Network with peers from other organizations.

PGHD coordinators benefit from peer relationships with colleagues from other practices who have done this type of work, bringing back lessons learned and use case ideas, among others.

Include Community Partner Organizations and Agencies

Practices can partner with local organizations such as public libraries and community centers to offer patients PGHD education and technical support. Mobile telemedicine technicians (MTTs) can provide patients with technical support in their homes. Payers may subsidize PGHD devices and apps. The Federal Communications Commission supports several programs intended to subsidize access to mobile devices and broadband connectivity for eligible patients.



Partnering with local organizations and stakeholders has demonstrated long-lasting health benefits to diverse groups of patients. For example, one study partnered with local barbershops to support blood-pressure reduction among Black male barbershop patrons. This collaboration resulted in significant blood-pressure reduction when coupled with medication management by specialty-trained pharmacists.³³ This is one creative partnership your organization could consider to strengthen your PGHD implementation and patient engagement.



Idea: Get insight from external partners.

Consider inviting external partners, such as representatives from your EHR vendor, medical device vendors, payers, and interested community stakeholder organizations to join your PGHD program planning and implementation team. Partners from organizations in your community, such as the library or public health department, might be able to partner with you to ensure health equity is a part of your PGHD implementation.



ACTIVITY 3.1: Assemble Your Team of Champions

Using the form below, enter the name of each champion in the provided blank. This is a comprehensive list intended to accommodate the wide variation in size and scope across ambulatory care practices. For smaller practices, individuals may assume multiple roles and responsibilities among those identified here.

Modify responsibilities to fit your practice needs, structure, and resources and choose champions from this list to form your core PGHD workgroup.

Instructions: Type names directly into the field or print to handwrite. Click the checkbox to indicate if this person(s) is a member of the core PGHD workgroup.

PGHD COORDINATOR

Name: _____

Core workgroup member

- Recruit and align stakeholders.
 - Support and manage team of PGHD implementation champions.
 - Help team effectively use QI and change management frameworks.
 - Provide structure to set program goals and measures of success.
 - Track key decisions, action items, and progress on meeting goals.
 - Help the team apply performance measure data to inform decisions and plans.
- Provide critical project management support.
 - Take user-centered approach to PGHD implementation, clinical decision support, data visualization solutions, and workflows to ensure clinicians and patients have the right data at the right time.
 - Serve as a point of contact for patients and staff participating in the design and implementation of the PGHD program.
 - Manage the team's overall work, including scheduling meetings, taking minutes, managing timelines and budgets, and activities.
 - Manage the implementation and ongoing monitoring of this improvement effort.
 - Manages staff and patient PGHD education, technical support, and troubleshooting.



FOLIO 3

Assembling a Team to Manage Change

- Develop cultural norms.
 - Build a library of clinical evidence for the value and necessity of PGHD.
 - Encourage staff to use PGHD in their own care.
 - Normalize PGHD as integral to routine care.
 - Standardize PGHD implementation trainings, practices, and messaging across the practice.
- Build policies and workflows.
 - Define terms of use for PGHD.
 - Establish processes for reviewing PGHD data uploaded into the EHR and responding in a timely fashion.
 - Design, test, and refine workflows for—
 - Gathering patient consent.
 - Prescribing PGHD devices and apps from a digital formulary.
 - Validating PGHD tools and devices.
 - Setting patient PGHD safety ranges.
 - PGHD triage and response.
 - PGHD applications in care management.
 - Develop documentation to support workflows with clear protocols and policies.
- Organize staff training.
 - Develop and updates trainings for staff, patients, and their families.
 - Increase staff familiarity with devices and methods for PGHD integration into the EHR.
 - Ensure support staff is familiar with how patients experience PGHD interfaces.
 - Coach staff on specific PGHD implementation.
- Track rates of PGHD uptake and patterns of use.
 - Report data from the EHR, patient surveys, and other sources to monitor the frequency and consistency of the data uploaded into the EHR by patients.
 - Track PGHD implementation performance metrics and provide progress reports.
 - Monitor clinicians' review of PGHD, including timeliness and frequency.



CLINICAL CHAMPION(S)

NOTE: Include clinicians and clinical support staff involved in PGHD implementation in your practice. (e.g., physicians, physician assistants, nurse practitioners, nurses, care managers, clinical pharmacists, medical assistants)

Name: _____

Core workgroup member

- Identifies clinical use cases for PGHD.
- Build a library of peer-reviewed clinical evidence to support PGHD implementation.
- Establish clinical criteria for PGHD triage and interpretation.
- Inform PGHD implementation policy, protocols, and data governance with clinical considerations.
- Participate in selecting a digital formulary of preferred PGHD devices, tools, and apps
- Consult on PGHD implementation workflows.
- Prescribe PGHD to patients.
- Communicate the value and necessity of PGHD in quality routine care.
- Engage and seek feedback from colleagues.
- Consult with informatics champion to determine goals for data visualization to support point-of-care decision making.

PATIENT(S)

NOTE: Include patients from your patient and family advisory council, if applicable.

Name: _____

Core workgroup member

- Serve as a voice for patients and patient experiences.
- Advocate for features and functionalities patients want and need.
- Participate in piloting and critiquing PGHD implementation from the patient perspective.



QUALITY REPORTING CHAMPION

Name: _____

Core workgroup member

- Ensure your practice meets PGHD implementation reporting requirements for regulatory programs, certifications, alternative payment programs (e.g., patient-centered medical home recognition, uniform data system reporting, accountable care organizations).
- Monitor for opportunities to participate in PGHD implementation incentive programs.
- Partner with EHR vendors to automate PGHD-related data capture for reporting purposes.

INFORMATION TECHNOLOGY CHAMPION

Name: _____

Core workgroup member

- Assess bandwidth and equipment needs in various settings (e.g., exam room, remote office, patient home).
- Consult on technology solutions and equipment vendors.
- Install, configure, test, and maintain PGHD implementation hardware and software.
- Support patients with initial setup/validation/calibration for prescribed remote monitoring devices, fitness trackers/wearables.
- Assist with staff and patient PGHD implementation training and troubleshooting.
- Coordinate with MTT assisting patients in their homes.
- Work with EHR vendor to ensure interoperability for seamless, bidirectional PGHD exchange.

**INFORMATICS CHAMPION(S)**

Name: _____

Core workgroup member

- Partner with clinicians and the EHR vendor to automate clinical criteria for PGHD triage.
- Design effective dashboards or data visualization tools to present the right PGHD at the right time to inform clinical decision making.
- Work with clinician champion to identify segments of the patient population that are good candidates for PGHD.
- Participate in developing solutions to streamline interoperability between PGHD devices or apps and the EHR (e.g. SMART on FHIR APIs, SMART Markers). See the following sidebar for more information.
- Communicate the importance of ingesting PGHD as discrete data elements rather than free text.
- Advocate for standardized codes for PGHD-related services and procedures (e.g., CPT, SNOMED, LOINC).

SMART Health IT

SMART (Substitutable Medical Applications, Reusable Technologies) on FHIR (Fast Healthcare Interoperability Resources) APIs (Application Programming Interfaces) bridge health IT applications with various EHRs through an open, standardized platform that leverages reusable interface components already built into an EHR.³⁴ By using the FHIR data standard to enhance interoperability, applications using SMART on FHIR can securely deploy within any EHR.

Built off the SMART on FHIR specification, SMART Markers is a mobile device software framework for the capture and submission of PGHD such as PROs, health tests, and measurements. By streamlining interoperability, SMART Markers stand to improve PGHD app end-user experience for both patients and clinicians.³⁵



BILLING/FINANCE CHAMPION

Name: _____

Core workgroup member

- Stay current on PGHD billing and reimbursement policies and rates (local, regional, State, Federal, CMS, Medicaid, private payer).
- Ensure billing codes and modifiers (e.g., ICD-10, CPT, SNOMED, LOINC) are optimized for reimbursement and data collection purposes.
- Track PGHD-related costs, fees, penalties, incentives, revenue and variable financial dynamics.
- Monitor for PGHD implementation incentive opportunities with private payers or major employers.
- Project PGHD implementation return on investment (both revenue and cost savings).

LEGAL CONSULTANT

Name: _____

Core workgroup member

- Ensure legal and regulatory compliance with Federal, State, and payer guidelines.
- Vet vendors and providers; negotiate and manages external contracts.
- Oversee Business Associate Agreements and Data Use Agreements with contracted device and app vendors.
- Review liability and cybersecurity issues related to PGHD implementation.
- Advise on top-of-license clinical support staff functions related to PGHD implementation.
- Consult on legal aspects of PGHD implementation policies, protocols, and workflows.



EXECUTIVE SPONSOR/OPERATIONS CHAMPION

Name: _____

Core workgroup member

- Liaise between executive leadership and PGHD Implementation Team of Champions.
- Advocate for PGHD implementation resources and policies.
- Tout benefits of PGHD implementation from C-suite standpoint.
- Facilitate cultural acceptance/normalize change/leadership buy-in.
- Create budget and projections for maintenance and growth.
- Ensure staff and patients have appropriate hardware, software, infrastructure and capacity to collect, transmit, interpret, and store PGHD.
- Support processes that fulfill needs for quality reporting.
- Partner with organizations to assist patients facing barriers to using PGHD.

EHR VENDOR REPRESENTATIVE

Name: _____

Core workgroup member

- Partners with clinicians, informaticists, and IT specialists to pair existing and native EHR features to support clinical use cases for PGHD implementation.
- May offer a menu of proven interoperable PGHD apps and devices (e.g., SMART on FHIR gallery).
- May offer “plug and play” PGHD kits with one or more devices tailored to specific clinical applications.
- May offer solutions to ingest or translate PGHD in languages other than English.
- May offer staff technical training and support.
- May offer patient education and technical support.



FOLIO 3

Assembling a Team to Manage Change

COMMUNITY PARTNER ORGANIZATIONS AND AGENCIES

List potential partner organizations and agencies:



ACTIVITY 3.2: Assemble a PGHD Workgroup

Fill in the table with the core members belonging to your PGHD workgroup. Core workgroup members will work together to coordinate and facilitate planning and implementation.

Your core workgroup may include a mix of champions and other representatives who will support your PGHD implementation.

Instructions: Type names directly into the field or print to handwrite.

CORE PGHD WORKGROUP MEMBERS

Executive Sponsor: _____

PGHD Coordinator: _____

Patient Representative(s): _____

Practice Manager/Operations: _____


Quality Reporting: _____

Health IT: _____

Billing/Finance: _____

Other: _____

Other: _____



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*

FOLIO 4: Making the Right PGHD and Information Technology Decisions for Your Practice



FOLIO 4

Making the Right PGHD and Information Technology Decisions for Your Practice

Estimated reading time: 11 minutes

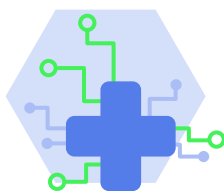
IN THIS FOLIO

Key Learning Concepts

- Identify information technology best suited to your PGHD implementation.
- Legal, compliance, and security factors must be considered ahead of implementation.

Active Learning Exercises

- ACTIVITY 4.1: Roadmap to PGHD Implementation: Key Health IT, Legal, Compliance, and Security Considerations



Choose Information Technology that Meets Your Needs

Your practice has choices to consider concerning the devices and instruments to use in your PGHD program. A good place to start is with your EHR and your EHR vendor.

Reach out about the following:

Compatibility With Your EHR

As described in **Folio 1**, there are various types of PGHD and different ways to get these data into your EHR. Which types of PGHD are ingestible into your EHR? Determine the types that are supported, how these data are ingested or entered into the EHR, and how these data populate (e.g., discrete field, text data). Which digital PGHD devices, apps, and smartphone operating systems are most compatible? Compatibility should be assessed for devices in terms of whose products produce data that can be easily integrated into the EHR via the patient portal.

EHR functionality for visualizing PGHD

Determine which native PGHD integration features are included in your EHR package, such as visualizations and flagged data elements. Does your EHR have built-in dashboards, graphs, pie charts, or other data visualization tools to help clinicians more efficiently interpret PGHD? Are there PGHD data visualization solutions available to help patients use their own data to better manage their health?

Building your own customizations

You may want to talk with your EHR vendor about developing customized ways of ingesting PGHD and displaying these data on dashboards for viewing PGHD in the patient chart. If you want to pursue a custom build, find out how long it will take and what costs are involved. If your practice has a vendor relationship with a population health aggregator, consider reaching out about visualization options.

Cost

Whether you would like customization or not, be sure to talk with your EHR vendor about cost, as functions related to integrating PGHD into your EHR are likely to have a cost. See **Folio 5: Evaluating the Costs of PGHD Implementation** for more information.

Selecting Devices for Your PGHD Program

By consulting with your EHR vendor to identify the best device options for your EHR, you will narrow your range of options. You may want to test some sample devices to compare quality, costs, usability, and functionality on different mobile devices, such as iPhone and Android smartphone platforms. Your selection decisions should also be informed by the following considerations. For specific considerations, see **Activity 4.1**

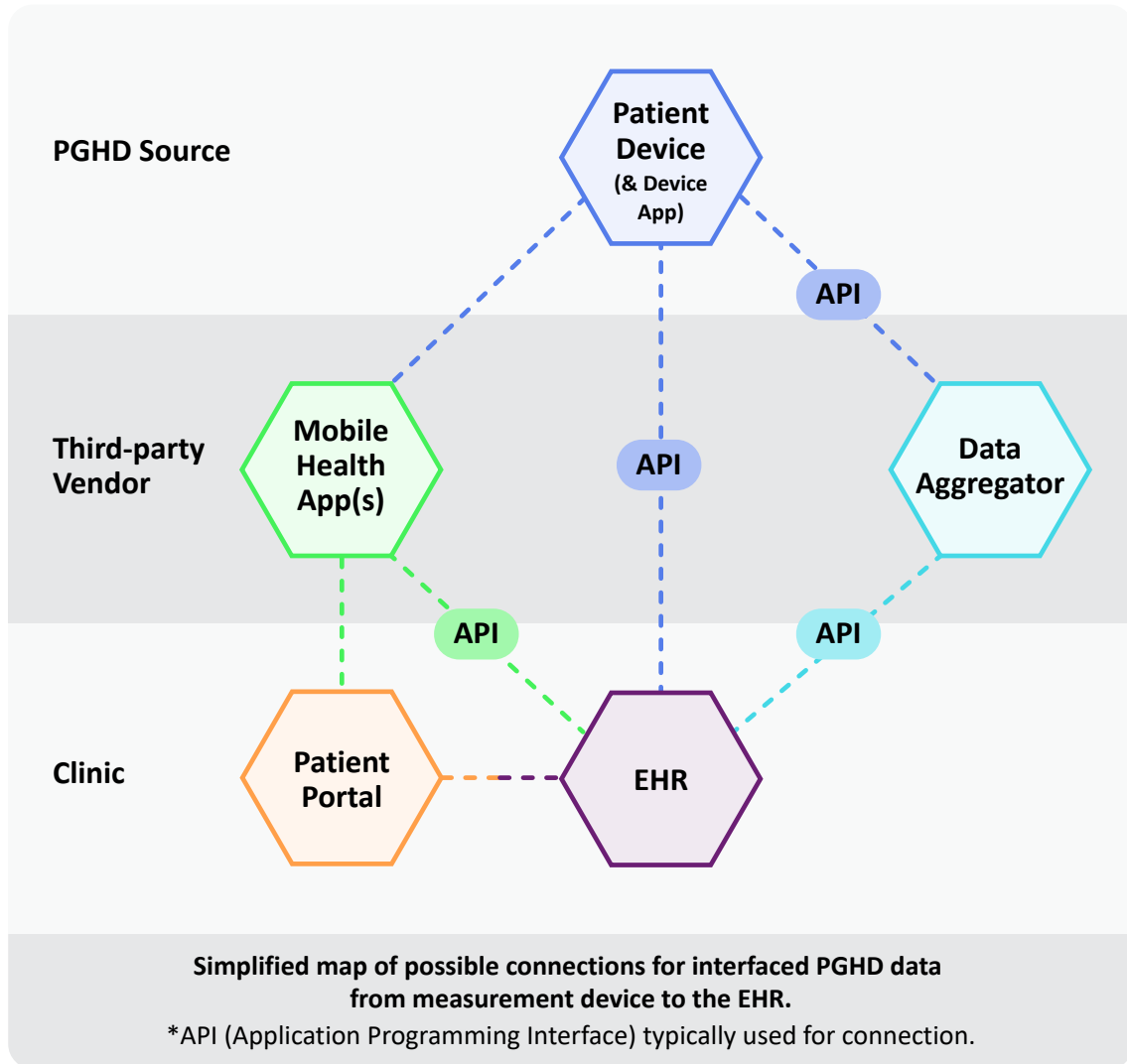


Tip: The good news is that you do not have to do all this research and testing yourself. Some EHR vendors furnish PGHD device kits tailored to specific clinical conditions. There are also third-party vendors who offer PGHD packages and/or facilitate EHR integration. Identifying these available options will significantly lighten your workload.

Pathways to PGHD Integration into the EHR

PGHD integration is often complex and dynamic. Some vendors facilitate the integration of data into the EHR directly, while others may require the use of a third-party aggregator that accepts the PGHD data from devices and prepares the data for upload. Additionally, the patient portal may be utilized for patient identification and other communications. **Figure 1** illustrates a simplified connection network that PGHD might follow between the patient's device (or app) and the EHR.

Figure 1. Simplified Connection Network Between a Device and the EHR



Carefully Evaluate PGHD Apps, Devices, and Instruments

There are a staggering number of consumer health apps. Some of these apps meet the FDA's definition of a medical device. The majority of mHealth apps are not regulated at all. Some meet HIPAA compliance for security and privacy, but most do not. There are currently two smartphone operating systems—Apple iOS and Android—that can facilitate seamless interoperability between many mHealth apps and various EHRs. Further, some apps collect PGHD as free text, and others collect responses as discrete data elements.

Consider Your Approach to Patients Choosing Their Own Devices

Another key consideration is whether your practice is open to a “bring your own device” (BYOD) model in which patients may use the device or app of their choosing for integrating PGHD into your EHR. BYOD offers patients the advantage of flexibility and fosters a patient-centered approach. On the other hand, a BYOD model may make it more challenging to ensure data quality and seamless integration into the EHR.

Be mindful of scenarios that call for multiple devices. This will increase the complexity for both your practice and your patients. For example, while kits of devices can be helpful for patients to track COVID-19 symptoms (digital thermometer, blood pressure cuff, and pulse oximeter) or diabetes (wireless glucometer, blood pressure cuff, and weight scale), they also require sophisticated patient tracking of data from each device and a more complex and timely process for uploading data via the portal for each device.



Idea: Use a digital formulary.

Consider using a digital formulary of validated devices and screening instruments for certain types of PGHD, such as a specific wireless glucometer that is an FDA-regulated medical device used to help manage diabetes; and also allow patients to use unregulated consumer mHealth apps to track calories, sleep patterns, or moods.



Tip: Start a patient lending library of devices, such as validated wireless blood pressure cuffs, glucometers, and pulse oximeters, to address potentially prohibitive equipment costs for some patients.

Legal, Compliance, and Security Frameworks

Developing a legal, compliance, and security framework within which to operate your PGHD program is key for your executive team. Because Federal, State, and payer policies are continually evolving, this section summarizes just what we know today. You can leverage your stakeholders, staff, and external partners to help keep your practice up-to-date on new developments in these areas.

**Practice-Level Policy and Protocols**

Your practice may want to pay particular attention to the legal and financial policies that may impact the use of PGHD in your practice, as well as rules pertaining to the security and privacy of data moving from the patient to the practice.

Legal and Compliance Considerations

Ideally, a designated staff member or a contracted expert will be available to review all policy and protocols for compliance with regulatory requirements such as HIPAA requirements. Adhering to legal and regulatory requirements will protect your practice from reprimands, fines, or reputational damage. Continually evaluate your PGHD project against current and upcoming local, State, and Federal changes.

Provider-Level Medical Insurance

Another consideration for PGHD integration is practice- and provider-level medical insurance. Be sure to check that your insurance covers any liabilities from PGHD use for clinical care, including cybersecurity coverage.

Consent

Finally, work with your legal and compliance team to ensure that proper consent is collected from adults and minors with respect to PGHD. For example, the Children's Online Privacy Protection Act requires parent or guardian consent before collecting personal identifiable information from patients under 13 years of age.³⁶

Legal and Compliance Resource

[Center for Connected Health Policy](#)



Data Governance

Establishing a data governance plan will help you build an organization-wide framework of policies and standards to manage and protect your health information data assets.³⁷ A data governance plan can also help you inform policies and protocols to establish your practice's response time to address abnormal PGHD values. It will also help your practice set patient expectations about such things as terms of use for PGHD in clinical care, turnaround time for communications, and instructions for urgent or emergent symptoms related to PGHD.

Consider building a data governance framework that can help your practice with the following topics:

Patient Consents

It may be necessary to obtain signed privacy and security consent forms from your patient population. For example, rules for collecting and sharing PGHD may differ for pediatric patients with type 1 diabetes using continuous glucose monitors compared to adult hypertension patients uploading information into their patient portal.

EHR Ingestion

Your practice may find it useful to set parameters around how often certain types of PGHD should be ingested into the EHR. PGHD may be collected and transmitted daily, weekly, or monthly. Devices such as heart monitors can transmit data every few seconds. In such instances, data governance may help determine the binning algorithms to manage large volumes of data. Ensure that data do not become too abundant and indigestible to the clinical care teams.

Data Quality

In the context of PGHD integration into the EHR, data governance can help ensure that PGHD is reliable, validated, timely, and clinically actionable. It may determine how often your practice sends PGHD requests, PRO surveys, or other prompts for patients to provide PGHD. Your data governance plan can include specifications for the length of survey instruments and free text data elements.



Use of PGHD within the EHR

Your data governance plan can frame decisions about how your practice uses such things as automation to streamline processes, data visualization, and data aggregation—potentially from multiple sources—to help clinicians efficiently parse out the most significant data and trends for clinical decision making. What is the ideal data density to ensure clinicians do not miss key indicators? How might these parameters vary between patients?

Privacy and Security

Concerns about patient privacy and security surround PGHD. All data are subject to security risks. PGHD have unique vulnerabilities to consider when integrating them into the EHR. This includes the transmission of the data, reliance on vendors, device management, and use of cloud-based services. A security breach could compromise the integrity of the data and subject patients to data theft. It is a good idea to rely heavily on your health IT expert to continually monitor the integrity of these processes while ensuring that patients upload their data exclusively through the patient portal or secure application programming interface (API).

Federal and State regulatory oversight may become more standardized as broader adoption grows, particularly pertaining to consumer health devices. In the meantime, it can be difficult to assure patients, clinicians, and practices that PGHD are private and protected. This is what we know so far.

HIPAA

The Health Insurance Portability and Accountability Act of 1996's (HIPAA) Privacy and Security Rules apply to PGHD when data become part of your practice's health record. PGHD should be de-identified in transit, which flow from the patient's device, often via multiple intervening connections into the practice's EHR. Because the practice cannot control each step of this process, it is crucial to seek HIPAA-compliant vendors and platforms that perform privacy and security measures such as encryption. As noted by the Office of the National Coordinator for Health Information Technology (ONC), prior to reaching the EHR, PGHD are open to higher security risk because they are not necessarily protected by the same HIPAA regulations, potentially increasing their vulnerability to cyber threats and breaches.³⁸

To comply with HIPAA regulation, it is prudent to work with your practice's security and IT

staff to ensure safe transit of PGHD into the EHR through appropriate physical, technical, and administrative safeguards.



Tip: When using third-party vendors that will handle protected health information, use a Business Associate Agreement to stipulate that security and privacy practices of the vendor uphold HIPAA regulations.



Idea: Bolster your data security with available resources.

SMART on FHIR technology, validated devices, and vetted third-party vendors help to protect your practice from increased risk. Use of the patient portal and certain APIs can be part of your practice's data security approach.

Beyond your efforts to secure data transmission, you may also consider making patients aware that cyber threats are a possibility that increases with device software maintenance and third-party management of devices and apps. Educating your patients about these risks and the measures they can take to minimize them can significantly reduce the likelihood of a security breach.

Addressing Common Misunderstanding of Data Security Among Your Patients

Patients sharing PGHD may have a limited or incorrect understanding of when data about their health are protected by law, and when they are not. For example, they may incorrectly think HIPAA provides standards for privacy and security in all contexts, where no such universal protections exist. They also might not know that HIPAA-covered entities such as a health practices cannot share patient data without their consent unless it is for treatment, payment, or other exceptions.³⁹ It is important to make sure patients understand how their data will be used, who will have access to it, and what protections exist.

Because the legal and policy environment around PGHD continues to evolve, practices with the capacity may consider assigning a staff role to monitor new developments in this area that may affect your programs and patients.



Tip: Leverage your stakeholder group for guidance and assistance. Convene representatives from the clinical team, patients, support staff, and legal and compliance to review your protocols and practices and look for gaps.

PGHD Privacy and Security Resources

Department of Health and Human Services (DHHS) Health Industry Cybersecurity Practices: [Managing Threats and Protecting Patients](#)

[DHHS HIPAA and Health Apps](#)

Office of the National Coordinator for Health Information Technology (ONC) and HHS Office for Civil Rights (OCR) [SRA Tool](#)

[Xcertia mHealth App Guidelines](#)

National Institute of Standards and Technology (NIST) Guidelines:

<https://www.nist.gov/programs-projects/security-health-information-technology>

<https://www.nccoe.nist.gov/sites/default/files/library/sp1800/rpm-nist-sp1800-30-2nd-draft.pdf>

<https://www.nccoe.nist.gov/healthcare/electronic-health-records-mobile-devices>



**ACTIVITY 4.1: Roadmap to PGHD Implementation:
Key Health IT, Legal, Compliance, and Security Considerations**

Use the following list of key considerations to guide decision making and identify potential gaps in your PGHD program implementation.

These considerations will help form your customized roadmap to implementation and assist your work in **Folio 6, Activity 6.1: Bringing It All Together: Your PGHD Implementation.**

Instructions: After each consideration, use the form field to record notes. Type directly into the field or print to handwrite.

HEALTH INFORMATION TECHNOLOGY DECISIONS

Device Considerations

- Will you permit a BYOD model?
- Will you standardize a formulary of validated devices, screening instruments, and apps?
- Who manages the devices—the patient, the vendor, or the clinic?
- Will devices be bundled as part of a kit tied to a clinical focus?



- Does your EHR permit multiple device inputs for one patient?

Device Selection

- How will devices be integrated with the smartphone, computer, apps, and the EHR?

- Do devices connect via Bluetooth or a wireless network?

- Which devices work equally well on both iPhone and Android phones?

- Have devices been validated for accuracy? Can you locate evidence from the device vendor or elsewhere that demonstrates that the data collected are accurate?

- Do your payers have specific requirement for device use linked to reimbursement? For example, as of 2021, Medicare requires that medical devices supplied to patients for remote physiologic monitoring services are valid, reliable, and meet FDA criteria.



PGHD INTEGRATION INTO THE EHR CONSIDERATIONS

- What kinds of PGHD will you bring into the EHR?
- Which types of devices, mHealth apps, or interfaces do you intend to support?
- How are devices validated?
- Which staff will manage PGHD to EHR integration workflows?

ADDITIONAL CONSIDERATIONS

- What types of data can be ingested via your health information exchange?
- Which digital interfaces are compatible with your EHR?



- What kinds of digital visualization tools or dashboards might you use to interpret and monitor PGHD values? Might these data visualization tools have applications for patient education?

LEGAL, COMPLIANCE, AND SECURITY FRAMEWORKS

Legal Considerations

- Does monitoring the PGHD to be collected during the PGHD implementation require additional medical liability coverage?
- What are the Federal, State, regional, and local regulations and policies governing the PGHD to be collected in the implementation?
- How do you collect consent from adult patients?
- How do you collect consent from pediatric patients?



Data Governance Considerations

- Have you developed criteria to ensure data are clinically relevant, valid, accurate, and timely?
- Have you established safety ranges tailored to each patient?
- Can you automate methods to flag clinically significant data; parse signal from noise?
- Can you trace provenance of data (i.e., what is the data's origin and what steps took place for it to reach its destination)?
- Where do you house data in the EHR?
- Can you support active and passive PGHD integration?



- Can PGHD integration be independent of the patient portal?


Policy and Protocol Considerations

- What legal, regulatory, clinical, technological, patient safety, and communications policies and protocols need to be in place?
- What are the expectations and obligations for clinicians to respond to passive/continuous PGHD with abnormal values?
- How will patients reporting PGHD with abnormal values during off hours be managed?
- What is the course of action if a patient sending abnormal results does not respond to outreach?



Privacy and Security Considerations

- What issues might arise regarding patient privacy?
- How might PGHD integration into the EHR increase vulnerabilities to cyberattacks?
- What mitigation steps should be taken?
- How will you educate your patients about their protections under HIPAA?



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*

FOLIO 5: Evaluating the Costs of PGHD Implementation





Estimated reading time: 9 minutes

IN THIS FOLIO

Key Learning Concepts

- Identify factors that will influence your program's financial sustainability.
- Develop a budget to implement, grow, and sustain your program.
- Estimating initial and ongoing costs.
- Identify sources of funding and cost savings.

Active Learning Exercise

- ACTIVITY 5.1: Roadmap to PGHD Implementation:
Key Financial, Reimbursement, and Reporting Considerations



This folio will help you consider the financial costs and potential gains of your PGHD program.

Beginning with broader factors such as billing, reimbursement, return on investment (ROI), and funding sources that will impact your program, the remainder of the folio offers guidance on how to estimate the initial costs associated with PGHD implementation, as well as resources needed to maintain your PGHD program in the future.

As you read through this folio, keep in mind that PGHD program implementation is an organizational change that will involve all aspects and people in your practice. Work with your team to identify all of the different resources and staff support that you will need to get PGHD implementation off the ground.



Big Picture Factors that Influence Your Program's Financial Health

Billing and Reimbursement

Historically, many PGHD-related clinical activities are not billable, and reimbursement rates for the PGHD activities that are billable do not generate enough direct revenue to offset costs. However, as digital healthcare solutions become more commonplace reimbursement for PGHD-related activities is increasing. Federal and State laws continue to evolve, particularly those that may cement payment parity for virtual care.

Medicare

Since 2018, the Medicare Chronic Care Management (CCM) program has reimbursed providers and care managers for collecting and interpreting PGHD in the management of hypertension, diabetes, asthma, and several other chronic diseases.⁴⁰

The Medicare physician fee schedule for calendar year 2021⁴¹ finalized reimbursement policies for remote physiological monitoring (RPM) services performed by both physicians and non-physician providers (NPP). These services may be medically necessary for acute care as well as managing chronic conditions.

Devices patients use for RPM services must meet the FDA's definition of a medical device. The patient must collect and transmit their PGHD electronically. [These rules](#) go into effect after the COVID-19 Public Health Emergency ends.



Medicaid

According to a 2021 survey conducted by the Center for Connected Health Policy (CCHP), Medicaid programs in 26 States reimburse for remote patient monitoring.⁴² Policies and rates of reimbursement for PGHD services vary widely from State to State. The CCHP updates its online State Telehealth Laws and Reimbursement Policies report twice per year.⁴³

Private Insurance

A growing number of private insurers offer subsidized fitness trackers and digital medical devices to incentivize participation in individual or employer-sponsored fitness and wellness programs. Many are also beginning to cover the use of RPMs to support chronic care management.

Your team's billing and reimbursement champion might investigate the opportunities to bill for services related to PGHD implementation. It will be crucial to determine the reimbursement rates for those services and restrictions tied to reimbursement. For example, reimbursement might be contingent on whether the service is rendered by a physician or NPP. It may depend on the particular device or app the patient uses to collect and share their PGHD. Your practice's payer mix will help guide where to focus research.

Explore Other Sources of Funding

Consider investigating other funding options that may supplement your program:

- Federal incentive programs designed to enhance interoperability.
- Federal, State, and local government agencies that may offer grant opportunities to support PGHD implementation.
- Collaborative relationships with community partners involved in conducting PGHD research or developing affiliated services to fund some of your PGHD activities.
- Funding from private foundations, including companies that manufacture PGHD devices and apps.
- Discount programs or price breaks may be available. For example, inquire with your EHR and medical device vendors about PGHD on large volume purchases of equipment or software licenses.



- Risk-sharing models or other value-based payment ideas with local payers and healthcare organizations. Such funding arrangements may provide incentives to integrate PGHD to improve care outcomes.

Return on Investment

ROI is a common analysis to gauge value. There are multiple ways to look at the financial ROI for PGHD programs in your practice. The billing and reimbursement champion on your team will be able to provide information about the payer rates of reimbursement for various PGHD related services. These figures can be used to develop projections for future PGHD-revenue streams based on anticipated billing volume.

At present, rates of reimbursement are relatively low and will likely not offset all costs related to your PGHD program. As this changes, consider the indirect cost savings generated by a PGHD program.

Estimating Indirect Cost Savings

If you have access to claims and/or EHR data and an expert data analyst, you may be able to guestimate some indirect cost savings. To do this, you may consider conducting some before and after comparative analyses of patients participating in your PGHD program on such topics as healthcare utilization and costs. Ideas you might investigate include the following:

- Frequency of in-office appointments and canceled appointments.
- Increased patient engagement and retention. ^{44 45}
- Better patient self-management and health outcomes.
- Fewer missed appointments.

In addition, systemic cost savings related to PGHD integration may be possible. ⁴⁶ Work with your payers to determine if there are shared benefits for your practice.



Incentive and Quality Reporting Programs

Many ambulatory care practices participate in quality reporting or incentive programs that include metrics on PGHD integration into the EHR.

Examples include:

- [Patient-centered medical home \(PCMH\) certification](#)
- [Health Resources and Services Administration \(HRSA\) Uniform Data System \(UDS\) reporting program](#)
- [Centers for Medicare and Medicaid Services \(CMS\) Clinical Quality Measures \(CQMs\) program](#)

Regional accountable care organizations as well as certain Medicare services, such as the Initial Preventive Physical Exam, Annual Wellness Visit, and CCM program, also require reporting on electronic PGHD integration into the EHR.

Examples of PGHD in Regulatory Reporting

As of 2020, the [HRSA UDS Controlling High Blood Pressure measure](#) will only accept blood pressure readings collected by a clinician or a remote monitoring device. This UDS measure aligns with [CMS clinical quality measure CMS165](#).

Under the Medicare Access and CHIP Reauthorization Act of 2015, CMS established a pair of payment structures to support RPMs. xv Eligible clinicians may participate in Medicare fee-for-service activities that reward use of PGHD through the Merit-Based Incentive Payment System (MIPS).

⁴⁷ Providers exempt from participating in MIPS may choose the Advanced Alternative Payment Models structure that provides financial incentives for using PGHD to offer more flexible and timely care that improves outcomes and reduces costs. ⁴⁸



Idea: Identify quality reporting programs with metrics that may include PGHD

It may be useful for your quality reporting champion to identify your practice's reporting programs that include digital PGHD metrics and the desired thresholds for each of these programs. Factor in this information as your team engages in writing aim statements and setting implementation goals.



Develop a Budget to Implement, Grow, and Sustain Your Implementation

After determining sources of revenue and funding from your PGHD implementation, it is necessary to evaluate its outgoing costs. To create your budget and projections, you will need to know associated implementation costs and maintenance fees for integration of PGHD into your EHR. These costs will vary depending on your practice, vendors, and choices. Examples of questions to ask your EHR vendor are offered in **Folio 4**. These questions will help you determine which PGHD devices and apps are compatible with your EHR, if there is another vendor (third-party) involved in PGHD integration with your EHR, and if your EHR vendor offers end-to-end support for certain PGHD medical devices or apps.

Use the following section as a guideline of considerations as you build the budget for your PGHD program.

Considerations for Your Cost Spreadsheet

When developing your cost spreadsheet for your PGHD program implementation, consider expenditures associated with your EHR, third-party device vendors, data aggregator, staffing, communications, and operations. The following lists provide examples of the types of costs you may want to account for when building out your budget. For each item, there may be initial costs, as well as those associated with scaling and/or maintaining your PGHD program in the long term. These are broken down into initial costs and ongoing costs.

NOTE: This list is not comprehensive and will need to be customized to meet the unique needs of your practice.



Initial Costs

1. Electronic Health Record

Additional costs may be associated with modifications to your EHR for PGHD integration and visualization. Talk to your EHR vendor to get an estimate of associated costs for the following:

- Updates, add-ons, and/or custom build for PGHD integration features.
- Data storage.
- Interfaces with application programming interfaces.
- Modules to support connectivity, documentation, visualization and interpretation.
- Fees for device bundles or kits.

2. Third-Party PGHD Device Vendors and Aggregator

Third-party PGHD device vendor and aggregator costs may include:

- New purchases of hardware and/or software.
- Workstation upgrades.
- Tablets.
- Devices.
- Software licenses.

3. Staffing

Consider if you have the capacity and expertise on staff to lead the PGHD implementation in-house, or whether you will contract with a consultant. If the latter, you will need to estimate consultant time and costs.

Staffing costs may include:

- Dedicated planning, testing, and implementation time.
- New roles added to staff model (i.e., PGHD Program Manager).
- Development and delivery of staff training.
- External contracts.



4. Communications

Consider the costs associated with building your communications plan regarding PGHD implementation and use. Communications will likely be targeted to practice staff and patients.

Examples of communications activity costs include:

- Patient-facing campaign to tout benefits and boost uptake of PGHD.
- Patient instruction materials in a variety of media and languages.
- Writing and publicizing success stories to gain PGHD implementation support.



Idea: Leverage experts to maximize reimbursement.

Some of these new costs might be offset by reimbursement. Engage the people in your organization with policy, reimbursement, and/or practice transformation expertise to assist with understanding these reimbursement opportunities. If your organization does not have this expertise in-house, consider identifying someone, such as a consultant, to help you taking advantage of all reimbursement opportunities available.

Ongoing Costs

There will be ongoing operational costs associated with your PGHD program that should be factored into longer-term budgets. These items will vary from practice to practice.

Examples include:

- EHR costs associated with maintenance and sustainability.
- Software and hardware upgrades.
- Per-transaction fees.
- Annual licensing fees and costs.
- Device replacements or upgrades.
- Refresher staff training courses.
- Periodic updates to communication materials.



Idea: Plan ahead for ongoing costs and reducing clinician burden

Consider including lines in your budget for ongoing staff training on evolving PGHD implementation best practices or scaling up your program. Your financial champion may also want to consider the financial implications of strategies to relieve clinician burden such as:

- Using clinical support staff working at the top of their licenses.
- Using triage pools to monitor and flag PGHD coming into the EHR.
- Developing algorithms and data visualization tools to efficiently use PGHD for clinical decision making.

Your practice may benefit from coordinating with other like practices engaged in PGHD integration, including possibly sharing PGHD coordinators across practices to help you build on and implement learnings from your peers. You may also consider engaging medical societies who can connect you to resources and other practices doing similar work. Finally, you may even be able to engage students from local colleges and universities to aid your practice in the design and/or evaluation of your new program.



ACTIVITY 5.1: Roadmap to PGHD Implementation: Key Financial, Reimbursement, and Reporting Considerations

Use the following list of key considerations to guide decision making and identify potential gaps in your PGHD program implementation.

These considerations will help form your customized roadmap to implementation and assist your work in **Folio 6, Activity 6.1: Bringing It All Together: Your PGHD Implementation.**

Instructions: After each consideration, use the form field to record notes. Type directly into the field or print to handwrite.

BILLING CONSIDERATIONS

- Which types of PGHD activities are billable and reimbursable?
- For billing purposes, does it matter which clinical role performs various aspects of the work?
- Do payers subsidize devices that generate PGHD?




FINANCIAL CONSIDERATIONS

- Do reimbursements for billable PGHD-related activities adequately offset costs/staff time?
- Will your practice create a loaner library to assist patients unable to afford validated devices?

REPORTING CONSIDERATIONS

- Which PGHD might be useful to capture for quality reporting or incentive programs?



Integrating Patient-Generated Health Data into Electronic Health Records in Ambulatory Care Settings: *A Practical Guide*



FOLIO 6: Steps to Successfully Implement a PGHD Program





Estimated reading time: 20 minutes

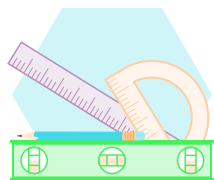
IN THIS FOLIO

Key Learning Concepts

- Set realistic and measurable goals.
- Effectively engage your target group of patients.
- Develop a workflow to support staff engagement and program design.
- Learn before scaling your PGHD program.
- Conduct rapid-cycle tests of change and applying end-user feedback.

Active Learning Exercises

- Activity 6.1: Bringing It All Together: Your PGHD Implementation
- Activity 6.2: Set SMART Goals
- Activity 6.3: Develop Workflows
- Activity 6.4: Evaluate and Refine
- Activity 6.5: Scale Up and Monitor



Developing Your PGHD Implementation

To this point, you have done pre-work in **folios 2, 3, 4, and 5** to focus and build your PGHD implementation. Use the activities at the end of this folio to bring all the pieces together.

Throughout this folio, an example of a PGHD implementation for patients with uncontrolled hypertension helps illustrate concepts such as developing SMART goals and using Plan-Do-Study-Act (PDSA) cycles.

Set Realistic and Measurable Goals for Your PGHD Implementation

Consider testing your PGHD implementation on a small scale before scaling up to other provider and/or patient groups. To move forward, it will help to break big goals into smaller parts. We recommend using the SMART goal framework for this task.

Figure 1. SMART Goals Framework





Engage the core PGHD workgroup to set your small-scale PGHD implementation goals and ensure they are realistic. Collectively determine what success will look like for your practice and how to quantify it.

The following is an example of a clinical use case being transformed into an implementation plan using the SMART framework.

The clinic has just been awarded a grant for the purchase of home blood pressure (BP) devices.

During our first stakeholder meeting, we decided to focus on a select set of hypertensive patients for our PGHD implementation. We chose hypertension because we have a large volume of our uncontrolled hypertension patients. We thought we would try incorporating PGHD in a small subset to see if we could move the needle before extending this intervention to a larger patient population. We also have a clinician who is very interested in championing this topic and has energized her team of medical assistants and the nurse pool about this endeavor.

Our goal is to provide 25 patients with Bluetooth-enabled cuffs to collect blood pressure readings that will integrate into the EHR within 3 months and then measure our target population's pre and BP measurements and their device usage data. We decided to also conduct post-intervention surveys to assess both the patient's and staff's satisfaction with our implementation. Our stakeholder team will then reconvene to review the implementation data and discuss next steps. The following example displays this use case using a SMART framework to support our implementation design and intervention.

A PGHD SMART Framework: Example

S – Specific: Improve BP in 25 patients with uncontrolled hypertension through PGHD.

M – Measurable: Patient BP and BP cuff device usage data are structured and easily retrievable. Survey responses can be summarized, and comments coalesced into prevailing themes.

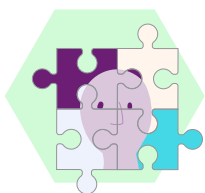
A – Attainable: Three months is adequate for our clinic to identify patients, disperse devices, and train participants. A subsequent 3 months is adequate to capture and review patient data, schedule followup appointments, assess performance using our metrics, and conduct and assess surveys.



R – Reasonable: It is certainly a worthy goal to improve BP in this population and reduce risk of cardiovascular events. This will also provide valuable insight into the use of PGHD in future population health initiatives.

T - Time-bound: These are clear and achievable. Six months is a tight cycle, but the program involves only a small group of staff and patients.

Activity 6.2 will guide you through a SMART goal activity on page 96. Methods and strategies for evaluation of goals will be discussed in the second half of this folio.



Effectively Engage Your Target Group of Patients

As one of the most important stakeholders in your implementation, it is essential to prioritize patient engagement with PGHD integration for your initial group and beyond. Patient input allows you to tailor your program to your patients' needs.

More information on selecting the initial group of patients to enroll in your program can be found in **Folio 2**.

When it is time to engage with your patients for your PGHD implementation, you could collect information using a patient focus group or through individual patient interviews to hear their interests, concerns, and questions about the specific project. We recommend asking patients the following questions as you develop your program.

- What reasons do you have to participate in a PGHD program?
- Do you have the desire to share digital data?
- Do you share data currently, such as bringing in handwritten logs, inputting data into the portal, or asking about health-related apps or devices?
- From your past experience with illness, what data would have been useful to share with your medical team?
- Do you have access to reliable internet and/or ample data plans?
- What is your comfort level with technology such as apps and devices?
- What are your communication preferences?



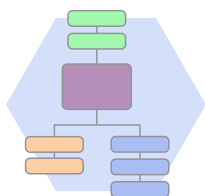
- In your opinion, would receiving patient digital health data help meet unmet care needs?
- What are your concerns about privacy and security?
- Do you worry about how much added time collecting PGHD will take?
- What else would you like the practice to know about getting digital data from patients?

**Idea: Provide training and support before patients use their device.**

Before sending patients home with a new device or app, offer opportunities for training and technical support. Make educational materials available in a variety of media and languages. Additional considerations should be given to those with dexterity, vision, or hearing impairments. Understanding cultural values can be very helpful as well. You might consider non-clinical resources to engage patients and improve adoption, such as working with community centers, faith-based organizations, even barber shops. ⁴⁹



Tip: Some practices have added mobile telemedicine technicians (MTT) to the care team or contract with third parties that furnish para-telemedicine services. MTTs travel to the patient's home to set up and troubleshoot technology to enable virtual care, including the use of remote monitoring devices. The MTT serves as an in-person liaison between the remote provider and the patient. In some models, MTT roles are filled by telehealth-enabled EMTs. ⁵⁰



Develop Diagrams and Detailed Workflows

Involving clinic staff in program design is an effective approach to build buy-in and increase program success. Develop and distribute detailed workflows based on input from all those impacted.

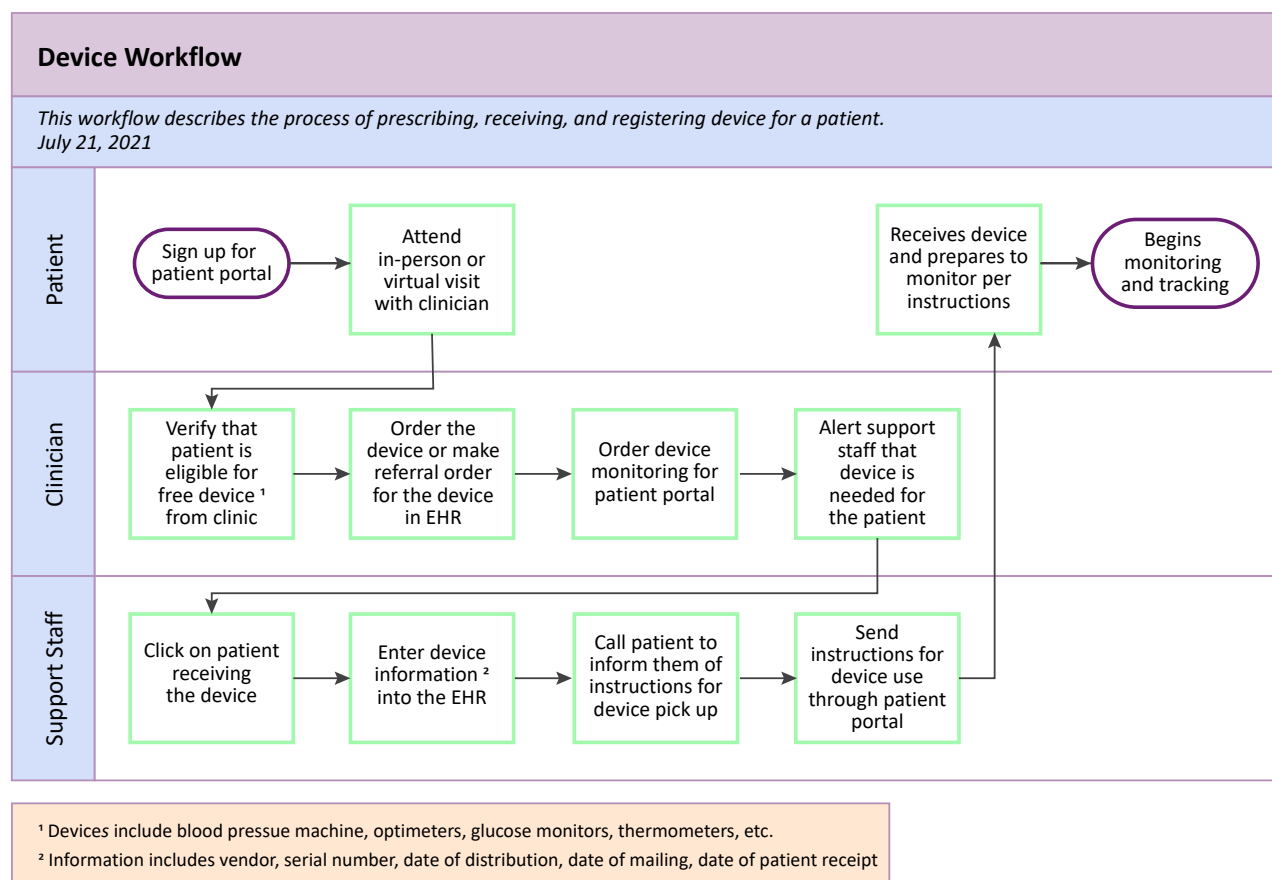


Swimlane Diagrams

Swimlane diagrams (also known as flowcharts) can be an effective way to demonstrate chronology and responsibility. This, combined with adequate time and training, can also help alleviate staff resistance to change. Each step in a process is identified by which role is responsible and at what point in the process it occurs. Icons can be used to further communicate about particular steps in the process, such as where the process starts and ends, if a decision needs to be made, or if another workflow needs to be referenced or used in between steps. For more information on how to build and use swimlane diagrams, see [AHRQ's Workflow Assessment for Health IT Toolkit section on flowcharts](#).

Figure 2 is an example of a swimlane diagram showing one clinic's workflow for getting an integrated device and instructions for use to a patient. **Activity 6.3** provides a blank swimlane diagram to practices thinking through a PGHD process.

Figure 2: Example Swimlane Diagram for Patient Device Workflow





Workflows are Integral to Success

The success of your program hinges on workflows that maximize ease and convenience for patients and minimize clinician burden by furnishing the right data at the right time to best inform clinical decision making. Workflows are simultaneously one of the most important and most challenging components of PGHD integration into the EHR. Workflows should be considered from the perspective of each stakeholder involved—support staff, clinicians, patients, and others. It is the workflow that will coalesce the technology, the culture, and the human factors that can make PGHD integration successful. Clinicians should be involved in clinical workflow development to address and resolve hesitations around added workload. While studies show mixed results, it is the hope that PGHD integration lessens clinician burden rather than exacerbates it.



Learn from Your Experience Before Scaling Your PGHD Implementation

So far, we have suggested starting with small scalable implementations to rapidly test change and focusing first on your simplest clinical use case for integrating PGHD into the EHR. The unique characteristics of your practice and the activities described in **Folios 2, 3, 4, and 5** should have helped you design your implementation. After implementation, it is time to collect feedback.

Collect Qualitative Input from End Users

While designing your implementation, you probably came up with quantitative goals to use to evaluate the impact of your program, like measuring blood pressure or HbA1c levels. It is important to also assess the qualitative impact of your program on both clinic staff and patients.



Some techniques include—

- Short user experience surveys or focus groups can be used to collect valuable information about what various end-users like about the PGHD integration process as well as aspects they would improve. Consider seeking patient input on their experience with the following topics:
 - Patients' ability to easily use and understand the device, including its interface and language settings.
 - Ease of uploading patients' data into the EHR via patient portal.
 - Frequency with which practices have asked patients to upload data.
 - Whether patients received timely and comprehensive technical support with device and patient portal setup.
 - Patient awareness about how their data are being used at the point of care.
- You may also consider soliciting feedback from all the involved staff members. Examples of questions you might ask include:
 - How satisfied are staff with training and onboarding into the program?
 - How well do workflows deliver actionable data for clinical decision making?
 - How well do staff understand patient eligibility criteria for participation?
 - How are those criteria are being using to screen for participation?
 - How comfortable are staff assisting patients with questions or delegating to designated technical support staff?
 - Do staff feel they have the technical skill to locate PGHD data in the EHR and visually display it in a way that is easy to interpret?

**Idea: PGHD Coordinators can help onboard new clinicians and patients.**

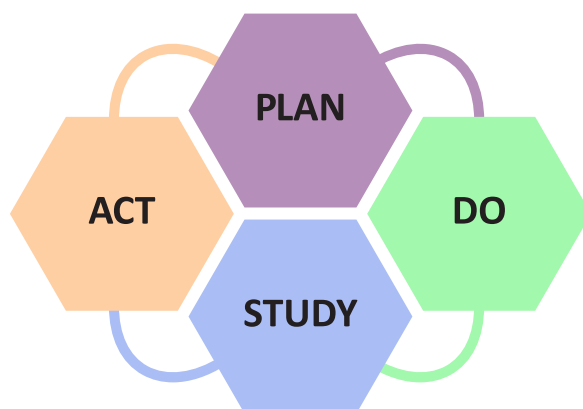
If you are a larger organization or plan to apply a PGHD program across multiple use cases, it may be beneficial to assign distinct PGHD coordinators to oversee and share responsibility. If you are a smaller organization and need to assign this role to clinical staff, you may want to monitor how much time this takes away from patient care. Ideally, your practice can identify nonclinical technical specialists with the expertise and dedicated time to focus on supporting patients and clinicians. These technical support staff may work with clinicians and patients on site, in the clinic, or virtually via phone or videoconference.



Tip: Ensure training and technical support resources keep pace with program expansion. Perhaps the most critical piece of scaling up is to ensure both staff and patients have abundant education to correctly use PGHD devices, apps, and instruments, as well as knowledgeable and timely technical support to help troubleshoot when things go wrong. Engaging care coordinators, home health providers, and community organizations can be helpful to serve as trainers or coordinators to augment clinic staff.

Rapid-Cycle Testing and End-User Feedback

As your practice tackles each benchmark, it can be helpful to borrow from a quality improvement framework to observe, learn, and iteratively refine processes through rapid-cycle testing. Conduct these rapid-cycle tests, such as a PDSA cycle, for only as long as necessary to see a consistent pattern emerge that can inform next steps. **Activity 6.4** offers a PDSA cycle template that can be used as you evaluate small changes.

**Figure 3. Plan-Do-Study-Act (PDSA) Cycle****PLAN**

- Choose a measurable change you would like to test. Remember to start small. This can be a minor tweak to a routine process.
- Determine the units of measurement you will use.
- Plan the actions to make this happen.
- Describe why you want to perform this change and what you hope to achieve.

DO

- Carry out your change.
- Collect data for analysis.
- Note pain points.

STUDY

- Study the data with your team to interpret the impact of the change.
- Identify what you have learned.
- Decide on next steps.

ACT

- Apply your learnings to plan your next change cycle.
- If you are satisfied with your results, halt your iterative cycles of change and go to implementation.



Let's continue with the hypertension program example to demonstrate observing, learning, and refining processes using this framework.

PLAN

To review, we came up with an implementation plan to provide integrated BP cuffs and introductory training to 25 patients over the first 3 months, followed by another 3 months of BP recordings, automated support, and periodic check-in phone calls from the pharmacist. Find more details for this stage of the cycle above on page 76, including the use of the SMART goal framework to manage goals.

DO

The plan was implemented, and we are now at the 6-month mark. Operational details for this stage of the cycle can be found on page 76 and 77, including the use of project management tools such as a Swimlane Workflow Diagram.

STUDY

We are ready to review the operational, BP, and qualitative survey data.

Operational Data:

- 21/25 patients completed the program, returning their devices and having a post-intervention visit with the clinician. Two devices didn't work adequately, one was lost, and one was broken.
- There were 56 critical alerts from 12 patients; 50 of them were appropriate and responded to within 2 business days.
- There were 11 alerts that were triggered due to a patient neglecting to indicate on their smartphone that their medication was taken for 5 days. Upon reaching the patients, they all reported 100% compliance but forgot about checking off the reminders on their phone.
- The pharmacist had a 40% connection rate with phone calls, averaged 1.8 successful calls per patient, and connected with 23/25 patients at least once.

**Blood Pressure (Outcome) Data:**

- 294 blood pressures were added to the medical record: 31% interfaced and 69% manual.
- 16/21 showed improvement post- vs pre-intervention 3-day average (average improvement 8.1/3.3mmHg), three mixed, two worse (overall change -5.9/-2.5).
- 11/21 uncontrolled hypertension patients are now controlled.
- Three cases of white-coat hypertension and two cases of resistant hypertension were added to the problem list.

Survey Data:

- Patient surveys were returned by 19/25 patients. Overall satisfaction score was 4.1/5. The main barrier identified was difficulty getting the cuff readings to sync with the portal. Many also found the process a little tedious, especially the educational materials and daily prompts. Facilitators included the phone calls and the IT help desk.
- Staff surveys were returned by 7/8 staff members and overall satisfaction was 3.9/5. The main themes identified EHR usability on the plus side and inadequate time to perform PGHD duties on the minus side.

ACT

Though clearly a truncated version of a real evaluation process, the data summary nevertheless highlights the vital information that can be obtained from the Study portion of a PDSA cycle.

How might this team act on this information?

- Appreciate the high patient engagement and continue to use phone calls as a way to keep folks engaged.
- Eliminate the compliance alerts. This is addressed with the phone calls anyway.
- Continue with the critical value alerts, but plan on carving out 30 minutes of protected time for responses and followup. Look further into the data to see if we can raise the alert limit.
- Celebrate the BP response, but there are still too many patients with uncontrolled hypertension. The clinical team will enhance the algorithm, extending the program for those who were making progress but didn't reach goal, while removing some of the automated content found to be more annoying than useful.



- Chart review of the five patients who had mixed or negative responses.
- Provide patient education and collaborate with their IT team and device vendor to get the percentage of electronically interfaced BPs over 50%.

Incorporate the suggested modifications and repeat testing for as many cycles as necessary. This process can be especially valuable to fine tune PGHD integration workflows.

When you are satisfied with the results within the limited group of providers and patients participating in your implementation, consider replicating it across other groups of providers and/or patients. This will enable you to validate that your PGHD solution performs well under a variety of circumstances and settings with different portions of your patient population. Based on findings from this round of testing, make further modifications as needed. **Activity 6.4** provides a blank PDSA template as an option to use in your practice.

Resources for Using PDSA Cycles

There are many resources and guidance on how to carry out PDSA cycles. Follow these links to learn more.

Institute for Healthcare Improvement (IHI): [Science of Improvement: Tips for Testing Changes](#)

IHI: [Why You Should Be Curious about PDSAs](#)

LifeQI: [Understanding PDSA Cycles](#)

LifeQI: [Benefits of PDSA Cycles](#)

AHRQ: [Health Literacy Universal Precautions Toolkit, 2nd Edition](#)

AHRQ: [Fillable Plan Do Study Act \(PDSA\) Tool for Health Care Quality Improvement \(QI\)](#)



Support Staff Awareness Through Training and Messaging.

Work with members on your team of champions to create documentation, training, and scripted messaging (discussed in the next section) to support uptake of this change among staff and patients. You are now ready to spread this tailored instance of PGHD integration broadly across your practice.

Scale with a Strong Internal and External Communication Plan

A coordinated communications plan customized for your practice will improve the chance of a successful PGHD implementation. It is also an essential component of a change management framework. Messaging around PGHD integration can influence attitudes and shape culture.

It begins with your statement of purpose that explains your practice's rationale for PGHD integration. Your team's communications champion might think about creating standard phrasing to use in staff education and training that focuses on the benefits of PGHD integration from the perspectives of the staff that might gain from using it in routine care.



Tip: Draw on past experiences developing promotional campaigns for new technologies and services. For example, your practice might have mounted a communications campaign to boost the use of your EHR's patient portal.

Consider creating scripts or talking points that staff can reference when speaking with patients about the benefits of PGHD integration. These can help prepare staff for fruitful conversations with patients who approach the care team about using PGHD in their care. Focus on real benefits patients will experience, such as:

- Collecting PGHD can provide data from your daily life to help your clinician see a fuller picture of your health.
- PGHD can support your self-management of [condition] and help you feel better.
- PGHD integration makes collecting data easy and convenient.
- We are here to partner with you every step of the way.

Scripting can also offer language that supports new cultural norms. For example, a medical

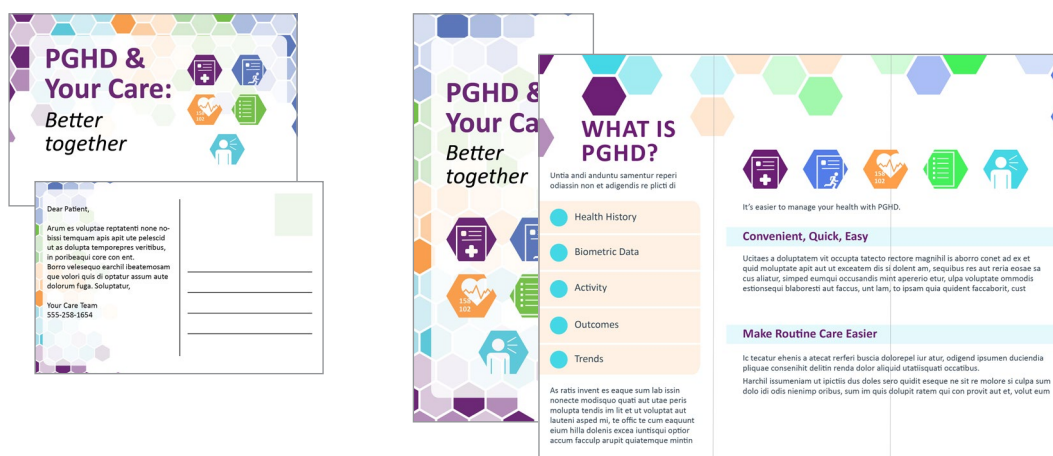


assistant might introduce the idea of using a wireless BP cuff to control hypertension by saying, “Your doctor would like you to try this easier way that we can monitor your blood pressure together, stay in closer touch, and more quickly make changes to your medications as needed.”

Encourage patients to participate in this new program by using various communication media. Here are some ideas:

- Create patient messaging that uses consistent language and graphics across multiple communications channels. These may range from printed patient education brochures and postcards to online information accessible via the patient portal or direct email messages

Figure 4. Sample Clinic PGHD Postcard and Brochure



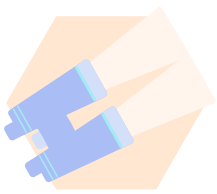
- Consider recording phone loops touting PGHD that patients can listen to while waiting on hold or video loops that can play on monitors in waiting rooms. What languages do your patient speak? If you have significant populations of non-English speakers, offer materials in languages that best accommodate your patients.
- Provide small incentives or rewards to patients who participate in the program, or clinicians who prescribe the greatest number of PGHD devices and apps, such as:
 - For Patients: small gift cards, gym passes, or other item from community partners.
 - For Clinicians and other care team members: lunch at a local restaurant, small care package, movie night bundle, or staff outing.



Share Success Stories

Develop mechanisms to reward milestone achievements, funnel clinician and patient PGHD integration success stories to your communications champion, and publicize positive outcomes. Personal stories of patients and clinicians experiencing success using PGHD in clinical care are key to spreading PGHD integration across your practice.

See **Activity 6.5** for potential considerations prior to scaling up.



Monitoring Environmental Factors

In addition to advancing technologies and trends, Federal and State policies impacting PGHD integration are in a period of flux. For example, Federal legislation, such as the 21st Century Cures Act, paved the way for new ONC interoperability standards and CMS rules that incentivize SMART on FHIR APIs (Substitutable Medical Applications, Reusable Technology (SMART) on Fast Healthcare Interoperability Resource (FHIR) Application Programming Interfaces (APIs)) to ensure that patients can easily access their health information data from the EHR via a smartphone app. It is anticipated that HHS will soon update HIPAA provisions to bolster patient health data privacy and security.

Staying current on this changing environment can help ensure that your practice's activities remain compliant with Federal and State rules, and that you can maximize available reimbursement.

Resources for Implementation, Scaling, and Environmental Monitoring Your PGHD Program

Take a moment to familiarize yourself with each of the links below. Bookmark those you find particularly useful and periodically return to them to keep up with this rapidly changing landscape.

Implementation and Scaling

- [Institute for Healthcare Improvement: Set-Up for Spread](#)
- [Institute for Healthcare Improvement: How-to Guide for Sustainability and Spread](#)
- [The Model for Improvement](#)



- Cambridge Management Sciences for Health: Implementing Best Practices Consortium: [A guide for fostering change to scale up effective health services](#)
- [Guide for monitoring scale-up of health practices and interventions: MEASURE evaluation](#)
- Management Systems International (MSI): [Scaling Up—From Vision to Large-scale Change: A Management Framework for Practitioners](#)

Environmental Monitoring

- The [Center for Connected Health Policy \(CCHP\) updates a report](#) twice a year on state telehealth laws and reimbursement policies.
- CCHP also maintains [a database](#) of federal telehealth laws and policies for Medicare and private payers.
- The [Federal Trade Commission offers an overview](#) of the laws that may apply to mHealth mobile apps and the various agencies that oversee compliance.
- Rock Health is a digital health venture capital firm that publishes [The Rock Weekly](#), a weekly newsletter about emerging developments in digital health technology.
- The [UCSF Center for Vulnerable Populations publishes research findings](#) about equitable digital health solutions designed to bridge the digital divide.
- The [Duke Mobile App Gateway for Digital Health](#) is a project of the Duke Clinical & Translational Science Institute (CTSI) focused on digital health and mobile health app research and innovation.
- The [Office of the National Coordinator for Health Information Technology \(ONC\)](#) maintains information about digital health technologies, policies, and regulations.
- [HIMSS Health App Guidelines Work Group](#) (formerly known as Xcertia) is a consortium of health leaders to create mHealth app guidelines and set standards for privacy, security, content, usability and other criteria.
- Centers for Medicare and Medicaid Services Electronic Clinical Quality Measures Resource Center continually updates its [FHIR education page](#) to assist with implementing this standard to accelerate data exchange. Find many open source tools to test and evaluate FHIR APIs.
- Health Level Seven International maintains [a webpage](#) and a Twitter feed (follow @FHIRnes using #FHIR) for updates on FHIR development.



ACTIVITY 6.1: Bringing It All Together: Your PGHD Implementation

At this stage, you have determined that integrating PGHD into clinical practice is a priority. We recommend starting with a small-scale implementation of PGHD integration to strengthen the plan before rolling out on a large scale. Use this activity to plan for your PGHD implementation.

As you begin this activity, reference your work from **Folios 2, 3, 4,** and **5** to build the PGHD implementation.

- Review the list of strengths, gaps, and resources needed to begin PGHD integration.
- Convene the core PGHD workgroup to create the PGHD implementation, identify resources needed, lead team members, and create an implementation timeline.
- The PGHD Coordinator leads brainstorming and guides action steps to build the PGHD implementation.

Instructions: After each consideration, use the form field to record notes. Type directly into the field or print to handwrite.

CONSIDERATIONS RELEVANT TO PATIENT PARTICIPATION

Designing the PGHD Implementation:

- Which patient populations will you target?
- How will patients be invited to participate?
- Who will be involved?



HEALTH IT DECISIONS

Designing the PGHD Implementation:

- Which PGHD will be collected?
- How will the practice receive PGHD?
- What data will be reviewed to monitor implementation?
- Who will be involved?

LEGAL, COMPLIANCE, AND SECURITY FRAMEWORKS

Designing the PGHD Implementation:

- Develop and distribute processes and standard operating procedures for consent, monitoring and outreach for the PGHD you will implement.
- Describe what happens when PGHD are clinically out of range. How are the data points identified? Who is notified? Who will follow up with the patient?



FOLIO 6

Steps to Successfully Implement a PGHD Program

- Who will be involved?

BILLING, REIMBURSEMENT, AND REPORTING CONSIDERATIONS

Designing Your PGHD Implementation:

- Will you bill for PGHD activities?
- What is your payer mix?
- What conditions that could benefit from PGHD do you bill for most often?
- Are you able to sustain the program until it becomes more cost efficient?
- How will you fund your program?



YOUR PGHD IMPLEMENTATION

Instructions: Type answers directly into the field or print to handwrite.

What

Target patient population: _____

PGHD to be collected: _____

PGHD Device: _____

PGHD out of clinical range: _____

Implementation tracking plan: _____

Team members involved: _____

How

Inviting patient participation: _____

Receiving PGHD: _____

Clinician and patient notifications: _____

Measures to monitor: _____

Team members involved: _____

Bring all the pieces together with a summary:

Your PGHD workgroup has developed the details for your PGHD implementation. Now your team can set a timeline to begin testing.

**ACTIVITY 6.2: Craft Your First SMART Goal**

Using your PGHD implementation plan, create a SMART goal for an initial benchmark in your PGHD program. Begin by identifying each element, and then bring them together to form your SMART goal.

Instructions: Type answers directly into the field or print to handwrite.

Benchmark goal:

S (Specific):

M (Measurable):

A (Attainable/Achievable):

R (Reasonable/Relevant):

T (Time-bound):

Synthesize the above for your SMART goal:









ACTIVITY 6.3: Develop Workflows

When mapping your workflow, give each role a swimlane, or row that contains each step that role takes throughout the task process. Place steps in a coded shape or icon to further indicate the type of action or decision necessary. For example, a capsule shape indicates the beginning or end of a process, and a diamond represents a decision point. See **Figure 5**.

The swimlane template on the following page (page 98) is intended for practice. It can be printed or edited directly in PDF reader software.

Figure 5. Icons for Workflow Swimlane diagram.

	Start or end of a process		Specific step, task, or activity within the process
	Point where a yes/no question is required		Reference or connection to another workflow
	Operational decision		Reference point that is not part of a decision point



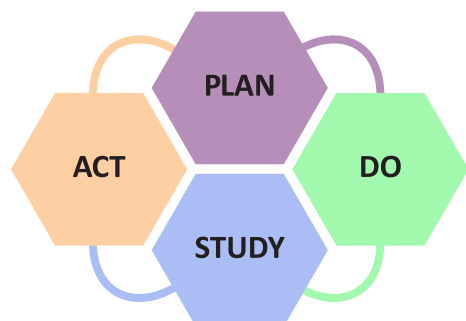
Instructions: Type directly into the workflow name, description, date, and role title fields or print to handwrite. Fill in tasks according to role and place in the process. Not all fields need to be filled in. Icons can be hand drawn or placed using some PDF reader software.

Workflow Name:	
<i>Description:</i> <i>Date:</i>	
Role 1:	
Role 2:	
Role 3:	

**ACTIVITY 6.4: Evaluate and Refine**

Use this PDSA template to perform successive rapid-cycle testing and track improvement for your PGHD implementation.

Instructions: Type answers directly into the field or print to handwrite.



Project Title: _____

Cycle Number: _____

Start Date: _____

End Date: _____

Brief description:

Objective for this cycle: Collect data Test a change Implement a change

Aim Statement: (Tip: Use a SMART goal):

Plan: Ask questions, predict results, determine what data need to be collected by whom.

Questions:

Predictions:

Data to be collected:



FOLIO 6

Steps to Successfully Implement a PGHD Program

Team and Assignments:

Do: Make the change/do the activity and collect data. Document what happened both positive and negative.

Positive +

Negative -

Study: Summarize your learnings, ask new questions, identify new issues. How does this compare with your predictions?

Learnings:

Results:

New questions/issues:

Act: Identify next steps based on your learnings.

Next cycle:

Team members:



ACTIVITY 6.5: Scale Up and Monitor

Once you have successfully implemented PGHD with a specific device and health condition with a small patient population, it is time to slowly scale up by expanding PGHD to more patients, more care teams, adding devices, adding health conditions, and so on. The method in which your organization scales up is flexible and can be tailored to your patient and clinic capacity.

Use the following checklist to determine key considerations with your PGHD team. Use **Activities 6.1-6.4** as you slowly scale up and expand your PGHD capacity.

Instructions: After each consideration, use the form field to record notes. Type directly into the field or print to handwrite.

PATIENT CONSIDERATIONS

- How do you want to scale up your implementation to a larger group of patients? Do you want to offer PGHD to a larger subset of patients? All of your patients with a specific chronic condition?
- How will this be communicated across patients? What health IT support will be in place for them?

TEAM MEMBER/STAFFING CONSIDERATIONS

- How do you want to scale up your implementation to a larger group of clinic staff? Do you want to expand your implementation to additional care teams, clinical groups, and/or across your organization?



FOLIO 6

Steps to Successfully Implement a PGHD Program

- What steps need to be taken to scale up staff training and messaging?
- In what ways will your internal and external communication plan need to be modified?

HEALTH IT CONSIDERATIONS

- What additional devices or apps would be most beneficial to your patients and staff next?
- How does your EHR support these devices and additional information?

LEGAL/ENVIRONMENTAL CONSIDERATIONS

- What, if any, internal and external legal, regulatory, clinical, technical, patient safety, communications, and protocols have been updated that may impact expanding PGHD?

FINANCIAL CONSIDERATIONS

- What funding and billing reimbursement guidelines best support expanding PGHD?

References

- 1 Shaw RJ, Boazak M, Tiase V, Porter G, Wosik J, Bumatay S, Michaels L, Stone J, Cohen D, Dolor R. Integrating patient-generated digital health data into electronic health records in ambulatory care settings: an environmental scan. Prepared under Contract 75Q80120D00019 / 75Q80120F32001. AHRQ Publication No. 21-0031. Rockville, MD: Agency for Healthcare Research and Quality. May 2021.
- 2 The Office of the National Coordinator for Health Information Technology. What are patient-generated health data? January 19, 2018. <https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data>. Accessed March 22, 2021.
- 3 Nichol JR, Sundjaja JH, Nelson G. Medical History. [Updated 2020 Sep 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK534249/>.
- 4 Houlden RL, Yen HH, Mirrahimi A. The Lifestyle History: A Neglected But Essential Component of the Medical History. *Am J Lifestyle Med*. 2017;12(5):404-411. Published 2017 Apr 11. doi:10.1177/1559827617703045
- 5 Walsh C, Elhadad N. Modeling clinical context: rediscovering the social history and evaluating language from the clinic to the wards. *AMIA Jt Summits Transl Sci Proc*. 2014;2014:224-231. Published 2014 Apr 7.
- 6 The Office of the National Coordinator for Health Information Technology. Patient-reported outcomes through health IT project. March 27, 2020. <https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-reported-outcomes-through-healthit-pro>. Accessed March 23, 2021.
- 7 The Office of the National Coordinator for Health Information Technology. Advancing the collection and use of patient-reported outcomes through health information technology: Final report. March 2020. Available from: <https://www.healthit.gov/sites/default/files/page/2020-03/ONCPROFinalReportFinal.pdf>
- 8 Osheroff JA, Teich JA, Levick D, Saldana L, Velasco F, Sittig D, Rogers K, Jender R. Improving Outcomes with Clinical Decision Support: An Implementer's Guide. 2nd Edition. Chicago, IL: HIMSS, 2012.

- 9 Kumar RB, Goren ND, Stark DE, Wall DP, Longhurst CA. Automated integration of continuous glucose monitor data in the electronic health record using consumer technology. *Journal of the American Medical Informatics Association*. 2016;23(3):532-537
- 10 Office of the National Coordinator for Health Information Technology. Conceptualizing a data infrastructure for the capture, use, and sharing of patient-generated health data in care delivery and research through 2024; White paper. January, 2018. Accessed on March 31, 2021. Available from: https://www.healthit.gov/sites/default/files/ncpghd_final_white_paper.pdf
- 11 Landi H. The business case for increasing patient portal adoption. [Blog post.] 2016. Retrieved from: <https://www.hcinnovationgroup.com/policy-value-based-care/article/13026197/the-business-case-for-increasing-patient-portal-adoption>.
- 12 Krist AH, Woolf SH, Rothenich SF, Johnson EE, Peele JE, Cunningham TD, et al. Interactive preventive health record to enhance delivery of recommended care: A randomized trial. *Ann Fam Med*. (2012;10(4), 312-319.
- 13 Zhou YY, Kanter MH, Wang JJ & Garrido T. Improved quality at Kaiser Permanente through e-mail between physicians and patients. *Health Affairs*. 2010;29 (7), 1370-1375.
- 14 Irving F. Why patient portals pay off. [Blog post]. 2019, November 6. Retrieved from <https://www.athenahealth.com/knowledge-hub/patient-experience/patient-portals-pay-off>
- 15 Lavalley DC, Lee JR, Austin E, et al. mHealth and patient generated health data: stakeholder perspectives on opportunities and barriers for transforming healthcare. *Mhealth*. 2020;6:8. Published 2020 Jan 5. doi:10.21037/mhealth.2019.09.17
- 16 Schwartz JE, Munter P, Kronish IM, Burg MM, Pickering TG, Bigger JT, Shimbo D. Reliability of office, home, and ambulatory blood pressure measurements and correlation with left ventricular mass. *J Am Coll Cardiol*. Dec. 22 2020; 76(25): 2911-2922. doi:10.1016/j.jacc.2020.10.039.
- 17 Fatani N, Dixon DL, Van Tassell BW, Fanikos J, Buckley LF. Systolic blood pressure in target range and cardiovascular outcomes in patients with hypertension. *J Am Coll Cardiol*. Mar 16 2021; 77(10): 1290-1299. doi: 10.1016/j.jacc.2021.01.014.

- 18 Ayala C, Tong X, Neeley E, Lane R, Robb K, Loustalot F. Home blood pressure monitoring among adults—American Heart Association Cardiovascular Health Consumer Survey, 2012. *J Clin Hypertens*. 2017;19: 584–591. DOI: 10.1111/jch.12983.
- 19 Technical Expert Panel Interview #2: Steven Kassakian (Portland, OR), Richelle Koopman (Columbia, MO), and Matthew Roman (Raleigh, NC), interviewed by Martha Snow (Portland, OR), March 11, 2021. Unpublished transcript. Oregon Health & Science University, Portland, OR.
- 20 USPSTF. High blood pressure in adults: Screening. October 12, 2015. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/high-blood-pressure-in-adults-screening-october-2015>. Accessed March 25, 2021.
- 21 Koopman RJ, Canfield SM, Belden JL, et al. Home blood pressure data visualization for the management of hypertension: Designing for patient and physician information needs. *BMC Medical Informatics and Decision Making*. 2020;20(1). doi:10.1186/s12911-020-01194-y.
- 22 Nundy S, Lu C-YE, Hogan P, Mishra A, Peek ME. Using Patient-Generated Health Data From Mobile Technologies for Diabetes Self-Management Support: Provider Perspectives From an Academic Medical Center. *Journal of Diabetes Science and Technology*. 2014;8(1):74-82. doi:10.1177/193229681351172]
- 23 Hardman, R., Begg, S. & Spelten, E. What impact do chronic disease self-management support interventions have on health inequity gaps related to socioeconomic status: a systematic review. *BMC Health Serv Res* 20, 150 (2020). Available from: <https://doi.org/10.1186/s12913-020-5010-4>
- 24 Lee J, Koh J, Kim JY. Popularization of Medical Information. *Healthc Inform Res*. 2021;27(2):110-115. doi:10.4258/hir.2021.27.2.110
- 25 Anita Ramsetty, Cristin Adams, Impact of the digital divide in the age of COVID-19, *Journal of the American Medical Informatics Association*, Volume 27, Issue 7, July 2020, Pages 1147–1148, <https://doi.org/10.1093/jamia/ocaa078>.
- 26 Lai, J. and Widmar, N.O. (2021), Revisiting the Digital Divide in the COVID-19 Era. *Appl Econ Perspect Policy*, 43: 458-464. <https://doi.org/10.1002/aepp.13104>
- 27 Lopez L, Hart LH, Katz MH. Racial and Ethnic Health Disparities Related to COVID-19. *JAMA*. 2021;325(8):719–720. doi:10.1001/jama.2020.26443

- 28 Rodriguez JA, Clark CR, Bates DW. Digital Health Equity as a Necessity in the 21st Century Cures Act Era. *JAMA : the journal of the American Medical Association*. 2020.
- 29 Dunn P, Hazzard E. Technology approaches to digital health literacy. *International journal of cardiology*. 2019;293:294-296.
30. Cohen DJ, Keller SR, Hayes GR, Dorr DA, Ash JS, Sittig DF. Developing a model for understanding patient collection of observations of daily living: A qualitative meta-synthesis of the Project HealthDesign Program. *Pers Ubiquitous Comput*. 2015;19(1):91-102. doi:10.1007/s00779-014-0804-1
- 31 Shaw EK, Howard J, West DR, et al. The role of the champion in primary care change efforts: from the State Networks of Colorado Ambulatory Practices and Partners (SNOCAP). *J Am Board Fam Med*. 2012;25(5):676-685. doi:10.3122/jabfm.2012.05.110281
- 32 Powell, B.J., Waltz, T.J., Chinman, M.J. et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Sci* 10, 21 (2015). <https://doi.org/10.1186/s13012-015-0209-1>
- 33 Victor RG, Lynch K, Li N, et al. A cluster-randomized trial of blood-pressure reduction in black barbershops. *New England Journal of Medicine*. 2018;378(14):1291-1301. doi:10.1056/nejmoa1717250
- 34 Computational Health Informatics Program. What is smart? SMART Health IT. March 2018.
- 35 Sayeed, R., Gottlieb, D. & Mandl, K.D. SMART Markers: collecting patient-generated health data as a standardized property of health information technology. *npj Digit. Med*.3, 9 (2020). <https://doi.org/10.1038/s41746-020-0218-6>
- 36 Mulligan SP, Freeman W, Linebaugh C. Data protection law: an overview. Paper presented at: R45631. Congressional Research Service. <https://crsreports.congress.gov/product/pdf/R/R45631>.
- 37 Office of the National Coordinator for Health Information Technology. Patient Demographic Data Quality Framework: Data Governance. <https://www.healthit.gov/playbook/ambulatory-guide/introduction/>. Accessed May 14, 2021.

- 38 Health UDo, Services H. Examining oversight of the privacy & security of health data collected by entities not regulated by HIPAA. Washington, DC: US Dept of HHS. 2016
- 39 Stevens GM, Division AL. A Brief Summary of the HIPAA Medical Privacy Rule. 2003
- 40 U.S Centers for Medicare & Medicaid Services. Quality Payment Program. 2021; <https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020>. Accessed February 18, 2021.
- 41 CY 2021 Payment Policies Under the Physician Fee Schedule Final Rule/interim final rule. 84472 Federal Register / Vol. 85, No. 248 / Monday, December 28, 2020 / Rules and Regulations. Department of Health and Human Services Centers for Medicare & Medicaid Services 42 CFR Parts 400, 410, 414, 415, 423, 424, and 425. <https://www.federalregister.gov/documents/2020/12/28/2020-26815/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>.
- 42 Center for Connected Health Policy. Remote Patient Monitoring Medicaid Reimbursement. February 2021. <https://www.cchpca.org/policy-trends/>. Accessed May 13, 2021.
- 43 The National Telehealth Policy Resource Center. State Telehealth Laws and Reimbursement Policies. Center for Connected Health Policy; Spring 2021. <https://www.cchpca.org/resources/state-telehealth-laws-and-reimbursement-policies-report-fall-2021/>
- 44 Gallo A. The value of keeping the right customers. 2014, October 29. Retrieved from <https://hbr.org?2014/10/the-value-of-keeping-the-right-customers>
- 45 Reichheld F. Prescription for cutting costs: Loyal relationships. 2001. Bain & Co. Accessed May 11, 2020. <https://hbr.org/?2014/10/the-value-of-keeping-the-right-customers>.
- 46 Shaw RJ, Boazak M, Tiase V, Porter G, Wosik J, Bumatay S, Michaels L, Stone J, Cohen D, Dolor R. Integrating patient-generated digital health data into electronic health records in ambulatory care settings: an environmental scan. Prepared under Contract 75Q80120D00019 / 75Q80120F32001. AHRQ Publication No. 21-0031. Rockville, MD: Agency for Healthcare Research and Quality. May 2021.
- 47 Stowe, E. C., & Augenstein, J. (2018, March 20). CMS Introduces New Incentives for Remote Patient Monitoring. Retrieved from <https://www.lexology.com/library/detail.aspx?g=dab59b6d-b8c0-4bb1-a75a-dda2c001449f>

- 48 eHealth Initiative Foundation. The return on investment of patient-generated health data & remote patient monitoring. July 2018.
https://www.ehidc.org/sites/default/files/resources/files/ROIPGHD_7.26.18_final.pdf
- 49 Victor RG, Lynch K, Li N, et al. A cluster-randomized trial of blood-pressure reduction in black barbershops. *New England Journal of Medicine*. 2018;378(14):1291-1301. doi:10.1056/nejmoa1717250
- 50 Abrashkin, K.A., McBride, A.C., Slaboda, J.C., Kurliand, M., Abel-Bey, A., Turkistani, A., Finuf, K. & Pekmazaris, R. Emergency medical technician-facilitated telehealth visits: A new model to expand home-based primary care for homebound seniors. *Telehealth and Medicine Today*. 2020. 5(3).